

US3312023 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:01:52

All time stamps listed in this document are displayed in GMT

US3312023

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

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Participant ID

US3312023

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

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US3312023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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) 15 Feb 2021 21:39:33

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 21:39:33

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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) 15 Feb 2021 21:39:34

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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) 15 Feb 2021 21:39:33

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 21:39:33

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Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 21:39:33

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Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 21:39:33

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Condition	OCCASIONAL LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 21:39:33

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Condition	LUMBAR ARTHRITIS (OSTEOARTHRITIS)
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3312023

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:08
Height (xxx.x)	68 in
Weight (xxx.x)	184 lb
BMI (xxx.x)	28.03560 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:39:34

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 21:39:33

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Date of assessment (dd MMM yyyy) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:39:34

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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 ☒

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**Specify**

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**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) 15 Feb 2021 21:39:34

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

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

What was the participant's randomization number? 185641

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) 15 Feb 2021 21:39:34

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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) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:08
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	13:03 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:03
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 AUG 2020

What was the treatment time? (00:00-23:59) 12:32 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 12:32

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) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	11:33 (24 HR)
Collection date and time (derived)	11 AUG 2020 11:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:08	11 AUG 2020 11:08
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

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 17:01:52

**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

97.6 °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

11 AUG 2020 13:10

PC Open Date & Time

11 AUG 2020 12:52

PC Close Date & Time

11 AUG 2020 15:22

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	11 AUG 2020 17:59
PC Open Date & Time	11 AUG 2020 16:17
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:14

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 17:26

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 17:42

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> 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 <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	15 AUG 2020 17:24
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**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

16 AUG 2020 16:50

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**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

97.9 °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

17 AUG 2020 16:37

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 8

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):

PC Time Stamp

18 AUG 2020 19:20

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 13:10

PC Open Date & Time

11 AUG 2020 12:52

PC Close Date & Time

11 AUG 2020 15:22

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**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

11 AUG 2020 18:00

PC Open Date & Time

11 AUG 2020 16:17

PC Close Date & Time

12 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**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)

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 18:15

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**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)

3

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 AUG 2020 17:27

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**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

14 AUG 2020 17:43

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**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

15 AUG 2020 17:24

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**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

16 AUG 2020 16:50

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**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

17 AUG 2020 16:37

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**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 ☐

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 13:11
PC Open Date & Time	11 AUG 2020 12:52
PC Close Date & Time	11 AUG 2020 15:22

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**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 ☐

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 18:01
PC Open Date & Time	11 AUG 2020 16:17
PC Close Date & Time	12 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**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 ☒

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 18:16
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 17:01:52

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:27
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3715

EAB) (1725)

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

55 of 3715

EAB) (1725)

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

		Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 17:25	
PC Open Date & Time	15 AUG 2020 12:00	
PC Close Date & Time	16 AUG 2020 11:59	

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

57 of 3715

EAB) (1725)

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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 ☐



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

		Yes <input type="checkbox"/>
PC Time stamp	17 AUG 2020 16:38	
PC Open Date & Time	17 AUG 2020 12:00	
PC Close Date & Time	18 AUG 2020 11:59	

US3312023

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:01:52

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 19:21
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3312023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

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)	08 SEP 2020
Time of assessment (00:00-23:59)	09:34 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:34
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

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)	08 SEP 2020
Time of assessment (00:00-23:59)	11:17 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:17
Temperature (xxx.x)	98.0 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)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3312023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 10:46

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

US3312023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	10:09 (24 HR)
Collection date and time (derived)	08 SEP 2020 10:09

US3312023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:52	08 SEP 2020 09:52
Nasopharyngeal Swab 2	No		

US3312023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.0 °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 08 SEP 2020 11:19

PC Open Date & Time 08 SEP 2020 11:06

PC Close Date & Time 08 SEP 2020 13:36

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	08 SEP 2020 17:18
PC Open Date & Time	08 SEP 2020 14:31
PC Close Date & Time	09 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**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

97.8 °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

09 SEP 2020 18:40

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.8 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

10 SEP 2020 19:49

---

PC Open Date & Time

10 SEP 2020 12:00

---

PC Close Date & Time

11 SEP 2020 11:59

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US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 16:30

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:23

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 16:13

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 16:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 11:19

PC Open Date & Time

08 SEP 2020 11:06

PC Close Date & Time

08 SEP 2020 13:36

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**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

08 SEP 2020 17:18

PC Open Date & Time

08 SEP 2020 14:31

PC Close Date & Time

09 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**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)

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

09 SEP 2020 18:41

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**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)

42

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

10 SEP 2020 19:50

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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

40

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

11 SEP 2020 16:31

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**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

12 SEP 2020 15:23

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**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

13 SEP 2020 16:13

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**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

14 SEP 2020 16:58

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**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 ☐

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:20
PC Open Date & Time	08 SEP 2020 11:06
PC Close Date & Time	08 SEP 2020 13:36

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**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 ☐

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:18
PC Open Date & Time	08 SEP 2020 14:31
PC Close Date & Time	09 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**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 ☒

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:41
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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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US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:50
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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

EAB) (1725)

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US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 16:32
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

EAB) (1725)

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US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:24
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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 ☒

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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

EAB) (1725)

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US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 16:58
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59



US3312023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:33

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	09:18 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 09:18
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3312023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3312023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 18:08:35

Generated On: 09 Jun 2021 17:01:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	10:38 (24 HR)
Collection date and time (derived)	06 OCT 2020 10:38

US3312023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:39:34

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 16:11:54
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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

18 OCT 2020 09:01:00

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 12:00:57

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 NOV 2020 13:02:35
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 08:15:33

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59



US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2020 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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

04 DEC 2020 16:05:50

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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	10 DEC 2020 07:50:45
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 14:23:57

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 DEC 2020 00:03:34
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59



US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 07:18:44

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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

07 JAN 2021 08:13:05

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 08:09:03

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 11:51:38

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 07:50:57

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 07:28:42
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 FEB 2021 09:15:08
Patient Cloud Open Date & Time	11 FEB 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
138 of 3715	

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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

18 FEB 2021 07:34:44

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 13:55:41
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 13:54:01

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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

11 MAR 2021 11:32:02

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 MAR 2021 14:46:27

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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

25 MAR 2021 11:50:14

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 16:51:28
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 07:22:31

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59



US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 08:01:12

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 16:48:23

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 16:32:31

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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°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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 FEB 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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°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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 MAR 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 MAR 2022 23:59
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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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 ☐



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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="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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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="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"/>

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59
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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**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 ☐

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

10 OCT 2022 23:59

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US3312023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

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

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3312023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:01:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 13:54:15

US3312023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3312023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

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.*

US3312023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00-23:59)	09:25 (24 HR)
Collection date and time (derived)	05 MAR 2021 09:25



US3312023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 16:42:51

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3312023

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 16:42:51

Generated On: 09 Jun 2021 17:01:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

Was Contact Attempted? Yes ☐  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

**US3312023**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Date of Contact	06 OCT 2020
Time of Contact	10:26
Date and Time of Contact (derived)	06 OCT 2020 10:26
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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"/>

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input 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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US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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 06 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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 06 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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 06 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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 06 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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"/>

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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 06 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 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 06 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Date of Visit 06 OCT 2020

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

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

Date of Test 06 OCT 2020

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

Other, specify \_\_\_\_\_

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

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Date of Contact	12 FEB 2021
Time of Contact	12:03
Date and Time of Contact (derived)	12 FEB 2021 12:03
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>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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 12 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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



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Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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



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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 12 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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"/>

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 12 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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



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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 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 12 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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"/>

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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"/>

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 12 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
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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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 12 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
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 12 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 12 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
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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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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"/>

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

	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 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 17:22:47

Generated On: 09 Jun 2021 17:01:52

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"/>

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Date of Visit	16 FEB 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	16 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3312023

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	08 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3312023

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 FEB 2021
Day 5	Yes	20 FEB 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)	

US3312023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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	SICKD1

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 10:25
Height (xxx.x)	68 in
Weight (xxx.x)	184 lb
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3312023

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

06 OCT 2020



US3312023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 10:09
Height (xxx.x)	68 in
Weight (xxx.x)	182.2 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3312023

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 FEB 2021

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID SICKD28

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

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.*

US3312023

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection



US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID SICKD28

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

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.*

US3312023

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312023

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

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

Visit date (dd MMM yyyy)	12 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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US3312023

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Date of updated informed consent (dd MMM yyyy) 12 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) 12 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 \_\_\_\_\_

US3312023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	09:16 (24 HR)
Collection date and time (derived)	12 JAN 2021 09:16

US3312023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 17:22:48

Generated On: 09 Jun 2021 17:01:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	09:15
Collection Date and Time (derived)	12 JAN 2021 09:15



US3312023

Folder: Unscheduled 12 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Visit Date	12 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312023

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	09:32 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 09:32
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312023

Folder: Unscheduled 12 Jan 2021

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3312023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:42:07

Generated On: 09 Jun 2021 17:01:52

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3312023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

LEFT WRIST FRACTURE

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)

14 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

DIFFICULTY BREATHING

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)

08 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)

15 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312023

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 15:42:06

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AEID

Adverse event

BODY ACHES

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)

08 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)

15 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 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)	19 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:42:06

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

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

NEW LOSS OF SMELL

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)

08 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)

15 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 ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

NASAL CONGESTION

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)

08 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)

15 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

RUNNY NOSE

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)

08 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)

15 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Mar 2021 15:42:06

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

SORE THROAT

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)

08 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)

15 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

SHORTNESS OF BREATH

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 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)

06 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 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)	19 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 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)	15 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

MUSCLE ACHES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 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)

06 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 ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

BODY ACHES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 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)

06 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312023

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 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)	06 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

NASAL CONGESTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 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)

06 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID

Adverse event

RUNNY NOSE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 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)

06 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 ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID	
Adverse event	SINUSITIS
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)	08 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)	17 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID	USA-US300-2020-MRNA-1273-P30 1000027
Adverse event	TAKOTSUBO CARDIOMYOPATHY
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)	18 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	19 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	



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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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SAE REPORT  
SUBJECT US3312023

SITE 331

PI CARLOS FIERRO M.D.

SOURCE IS PHONE CALL WITH  
SUBJECT, NO MED RECORDS AT  
THIS TIME TO CONFIRM

66 Y/O HYPERTENSIVE,  
HYPERLIPIDEMIC WHO DURING  
EMOTIONAL DURESS AT 10AM  
ON 18DEC20 DEVELOPED  
MID-STERNAL CHEST PAIN  
THAT RADIATED TO HER LEFT  
BACK ALONG WITH  
DIAPHORESIS, NAUSEA,  
FATIGUE, NO URI SYMPTOMS  
NOR SHORTNESS OF AIR. SHE  
ACTIVATED EMS, WAS  
EVALUATED IN ER AT  
APPROXIMATELY 11AM AND  
WAS FOUND TO HAVE BP  
185/143, ELEVATED TROPONIN,  
CARDIAC ENLARGEMENT ON  
IMAGING, EF OF 25 TO 30% ON  
ECHOCARDIOGRAM, AND  
CLEAR CORONARY ARTERIES  
ON CARDIAC CATH. A  
DIAGNOSIS OF TAKOTSUBO  
CARDIOMYOPATHY WAS  
MADE. TREATMENT INCLUDED  
SUBLINGUAL NTG, LOVENOX,  
FENTANYL, VERSED,  
DISCONTINUATION OF  
LISINOPRIL AND INITIATION OF

US3312023

Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

---

METOPROLOL AND ASPIRIN.  
SYMPTOMS RESOLVED BY  
19DEC20. EF WAS UP TO 48%  
PRIOR TO DISCHARGE AND BP  
WAS AT 126/72. COVID TEST  
WAS NEGATIVE ON 17DEC20  
AND NEGATIVE AGAIN TODAY  
AS PART OF EMPLOYMENT  
CHECKS. SUBJECT BACK AT  
WORK TODAY AND REPORTS  
SYMPTOMATICALLY BACK TO  
PRE-EVENT BASELINE AND  
DENIES EDEMA.  
SAE OF TAKOTSUBO  
CARDIOMYOPATHY NR TO IP  
OR COVID. MEDICAL RECORDS  
PENDING.FOLLOW UP  
12JAN2021 MEDICAL RECORDS  
REVIEWED AND CONFIRM  
SUBJECT'S REPORT OF  
HOSPITALIZATION FOR  
TAKOTSUBO OR ACUTE STRESS  
CARDIOMYOPATHY ON  
18DEC20. SUBJECT DID NOT  
HAVE MI. INITIAL EJECTION  
FRACTION ESTIMATE ON  
CARDIAC CATH WAS IN 30 TO  
35 PERCENT RANGE ON  
18DEC2020, AND LATER  
ESTIMATED AT 48% ON  
ECHOCARDIOGRAM 19DEC2020.  
CARDIAC CATH SHOWED NO  
OCCLUSION OF CORONARY  
ARTERIES. SUBJECT WAS PUT  
ON METOPROLOL AND ASA AS

US3312023

Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

---

PREVENTIVE MEASURES AS A  
RESULT OF THIS EVENT, AND  
SHE REPORTS THAT AT  
FOLLOW-UP 05JAN2021  
LISINOPRIL 5MG QD WAS  
PRESCRIBED BY PCP. A  
FOLLOW-UP WITH  
CARDIOLOGY IS SCHEDULED  
FOR 12FEB21. SUBJECT IS  
WELL AT A VISIT AT SITE  
TODAY SAE OF TAKOTSUBO  
CARDIOMYOPATHY, G3, NR TO  
IP, WILL CLOSE AFTER CARD  
F/U.03/05/21: CARD F/U DONE,  
ECHO NORMAL. AE CLOSED  
PER PI

---

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

---

US3312023

Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

AEID	
Adverse event	SINUSITIS
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)	05 FEB 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)	18 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 12 Mar 2021 15:42:06

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

---

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

Yes ☒

No ☐

---

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

---

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication LIPITOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 18:08:34

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Name of Medication CELEXA

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 18:08:34

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Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication LOWER BACK PAIN

Dose per administration 50

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 (4)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 18:08:34

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Name of Medication HYDROCODONE  
(BITARATE/ACETAMINOPHEN)

Prophylaxis Yes ☐  
No ☒

Indication LEFT WRIST FRACTURE

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)		15 AUG 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 AUG 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 (6)

Data signed: (b) (4) 07 Apr 2021 18:08:34

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Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication LEFT WRIST FRACTURE

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)	21 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 SEP 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 (7)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication LEVAQUIN

Prophylaxis Yes ☐  
No ☒

Indication SINUSITIS

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 (7)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)		08 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 18:08:34

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication SINUSITIS/HEADACHE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)	07 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 18:08:34

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Name of Medication SEASONAL INFLUENZA  
VACCINE

Prophylaxis Yes ☒  
No ☐

Indication SEASONAL INFLUENZA  
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication ASA

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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 (10)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 18:08:34

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Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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 DEC 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"/>

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)	31 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication TAKOTSUBO  
CARDIOMYOPATHY

Dose per administration 0.3

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 (15)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication LOVENOX

Prophylaxis Yes ☐  
No ☒

Indication TAKOTSUBO  
CARDIOMYOPATHY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)	18 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 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 (17)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication TAKOTSUBO  
CARDIOMYOPATHY

Dose per administration 50

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 (17)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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 checked="" 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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 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 (18)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication VERSED

Prophylaxis Yes ☐  
No ☒

Indication TAKOTSUBO  
CARDIOMYOPATHY

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	18 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication AUGMENTIN (AMOXICILLIN/  
CLAVULANIC ACID)

Prophylaxis Yes ☐  
No ☒

Indication SINUSITIS

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 ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SINUSITIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)		05 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENTION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 07 Apr 2021 18:08:34

Generated On: 09 Jun 2021 17:01:52

	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)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

---

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) 05 Apr 2021 17:22:46

Generated On: 09 Jun 2021 17:01:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 AUG 2020	SURGICAL REPAIR LEFT WRIST FRACTURE	Adverse Event	
18 DEC 2020	CARDIAC CATHETERIZATION	Adverse Event	
19 DEC 2020	ECHOCARDIOGRAM	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:01:52

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

US3312023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:01:52

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 ☐

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

SAEID	USA-US300-2020-MRNA-1273-P301000027
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

SAEID	USA-US300-2020-MRNA-1273-P301000027
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/DEC/2020 10:49
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

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

SAEID	USA-US300-2020-MRNA-1273-P301000027
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/JAN/2021 16:06
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

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 17:22:49

Generated On: 09 Jun 2021 17:01:52

SAEID	USA-US300-2020-MRNA-1273-P301000027
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:43
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



Audit

US3312023 (Prod: Johnson County Clin-Trials)

**US3312023**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:01:52**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:57:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'US3312023'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:24:35

US3312023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:36:04

US3312023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:24:36

US3312023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	11 Aug 2020 17:36:04

**US3312023**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'SCRN'	System	11 Aug 2020 17:36:04

US3312023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:24:37

US3312023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '66'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17



**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'YEARS'	System	13 Aug 2020 13:55:17

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '66'	System	11 Aug 2020 17:36:45

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Female (F)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

US3312023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17



**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

US3312023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 13:55:17
	(b) (4)	

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

**US3312023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:01:52**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:55:17

US3312023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:36:45

**US3312023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:01:52**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'Aug 2020'	System	11 Aug 2020 17:36:45

**US3312023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:01:52**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '2020'	System	11 Aug 2020 17:36:45



**US3312023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:01:52**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Amendment 2 (2)' reason for change:	(b) (4)	
Data Entry Error	Christa Estrada (b) (4)	12 Aug 2020 21:10:57
User entered 'Amendment 1 (1)'	(b) (4)	
	Christa Estrada (b) (4)	11 Aug 2020 17:36:45
	(b) (4)	

US3312023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:52

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:36:45

**US3312023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:01:52**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:36:45

US3312023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:36:45

**US3312023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:01:52**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:36:45

**US3312023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:01:52**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:24:36

**US3312023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:01:52**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'I'	System	11 Aug 2020 17:37:07

US3312023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:01:52

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:37:07



US3312023

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:01:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:56:02

US3312023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:58:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:58:25
Data point term sent to Coder	System	13 Aug 2020 13:57:19
User entered 'Hypertension'	Karol Moore (b) (4)	13 Aug 2020 13:56:42

US3312023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:56:42

**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:56:42

**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 13:56:42

**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 13:56:42

**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:56:42

**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'Jan 2000'	System	13 Aug 2020 13:56:42



**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '2000'	System	13 Aug 2020 13:56:42

**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:56:42

**US3312023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:56:42

US3312023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:58:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:58:24
Data point term sent to Coder	System	13 Aug 2020 13:57:19
User entered 'hyperlipidemia'	Karol Moore (b) (4)	13 Aug 2020 13:57:13

US3312023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:13

**US3312023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:13

**US3312023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:13

**US3312023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:01:52**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 13:57:13



US3312023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:13

**US3312023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'Jan 2010'	System	13 Aug 2020 13:57:13

**US3312023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '2010'	System	13 Aug 2020 13:57:13

**US3312023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:57:13

**US3312023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:57:13

US3312023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:59:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:59:27
Data point term sent to Coder	System	13 Aug 2020 13:58:20
User entered 'anxiety'	Karol Moore (b) (4)	13 Aug 2020 13:57:29
	(b) (4)	

US3312023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:29

**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:29



**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:29

**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 13:57:29

**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:57:29

**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'Jan 2000'	System	13 Aug 2020 13:57:29

**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '2000'	System	13 Aug 2020 13:57:29

**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:57:29

**US3312023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:57:29

US3312023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:12:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:12:59
Data point term sent to Coder	System	13 Aug 2020 13:58:21
User entered 'occasional lower back pain'	Karol Moore (b) (4)	13 Aug 2020 13:58:06



US3312023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'un UNK 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:58:06

**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:58:06

**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 13:58:06

**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 13:58:06
	(b) (4)	

**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 13:58:06

**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'Jan 2020'	System	13 Aug 2020 13:58:06

**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '2020'	System	13 Aug 2020 13:58:06

**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:58:06



**US3312023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 13:58:06

US3312023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of lumbar spine - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 10:23:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 10:23:38
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	05 Nov 2020 11:49:01
' (Site from DM).		
Data point term sent to Coder	System	03 Nov 2020 19:28:55
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Karol Moore (b) (4)	03 Nov 2020 19:28:37
' answered with 'updated' (Site from DM).	(b) (4)	
Coding entries removed.	Karol Moore (b) (4)	03 Nov 2020 19:28:33
User entered 'LUMBAR ARTHRITIS (osteoarthritis)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Karol Moore (b) (4)	03 Nov 2020 19:28:33
' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applic	(b) (4), (b) (6)	22 Sep 2020 06:13:45
' canceled (Site from DM).		

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:52

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applic ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:13:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 11:16:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 11:16:39
Data point term sent to Coder	System	13 Aug 2020 14:03:36
User entered 'lumbar arthritis'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:02:44

US3312023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:02:44

**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:02:44

**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:02:44

**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:02:44

**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:02:44



**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'Jan 2017'	System	13 Aug 2020 14:02:44

**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '2017'	System	13 Aug 2020 14:02:44

**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 14:02:44

**US3312023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 14:02:44

US3312023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
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)	13 Aug 2020 14:04:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:04:28
Data point term sent to Coder	System	13 Aug 2020 14:03:36
User entered 'post menopausal'	Karol Moore (b) (4)	13 Aug 2020 14:03:05
	(b) (4)	

US3312023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:03:05

US3312023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:03:05

**US3312023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:03:05



**US3312023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:01:52**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:03:05

US3312023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:03:05

**US3312023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'Jan 2010'	System	13 Aug 2020 14:03:05

**US3312023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '2010'	System	13 Aug 2020 14:03:05

**US3312023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 14:03:05

**US3312023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered empty.	System	13 Aug 2020 14:03:05

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:04:16



**US3312023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '10:08'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:04:16

**US3312023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered '11 Aug 2020 10:08'	System	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '68' in	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:04:16
DataPoint set to visible.	(b) (4) System	11 Aug 2020 17:37:07

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '184' lb	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:04:16
DataPoint set to visible.	(b) (4) System	11 Aug 2020 17:37:07

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
Amendment Manager: User entered '28.03560'	System	16 Sep 2020 23:51:48
User entered '28.0'	System	13 Aug 2020 14:04:16
DataPoint set to visible.	System	11 Aug 2020 17:37:07

**US3312023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'kg/m2'	System	13 Aug 2020 14:04:16
DataPoint set to visible.	System	11 Aug 2020 17:37:07

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:04:16



US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:04:16

**US3312023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:04:16

**US3312023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'bpm'	System	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'breaths/min'	System	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:04:16

**US3312023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'mmHg'	System	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:04:16



**US3312023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User entered 'mmHg'	System	13 Aug 2020 14:04:16

US3312023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38

**US3312023**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:01:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:07:08

US3312023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:09:59
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 15:49:56
User entered '11 Aug 2020'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:07:08

US3312023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:01

US3312023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:01:52

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:01

US3312023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:01:52

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:01



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Folder: Screening

Form: Childbearing Potential

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If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:01

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:01:52

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:01

**US3312023**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:01:52**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:01

US3312023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:01

US3312023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:01:52

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:01

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

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**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43



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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4)	13 Aug 2020 14:10:43
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:43

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '0'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:10:43



US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:43

US3312023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:32:38
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:10:43

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:37:40

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:37:40

US3312023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	11 Aug 2020 17:37:40

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'VISIT1'	System	11 Aug 2020 17:37:40

US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:49:51

US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:35:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:35:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 16:49:51
User entered '185641' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:49:51



US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:49:51

US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	Christa Estrada (b) (4)	11 Aug 2020 17:38:01

US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	Christa Estrada (b) (4)	11 Aug 2020 17:38:01

US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:38:01

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:01:52**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:38:01

US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:38:01

US3312023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:52

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 17:17:13
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:17:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:31:35

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36



US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36
	(b) (4)	

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '10:08'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered '11 Aug 2020 10:08'	System	13 Aug 2020 14:20:36



US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '98.3' F	(b) (4)	13 Aug 2020 14:20:36
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '70'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'bpm'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'breaths/min'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '140'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36



US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'mmHg'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '78'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'mmHg'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36



US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 07:09:30
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 14:20:36
User entered '13:03'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered '11 Aug 2020 13:03'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '97.6' F	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '67'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'bpm'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36



US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'breaths/min'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '154'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'mmHg'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '87' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 19:54:48
User entered '92'	Monica Atwood (b) (4)	02 Feb 2021 19:54:48
	(b) (4)	
	Karol Moore (b) (4)	13 Aug 2020 14:20:36
	(b) (4)	

US3312023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'mmHg'	System	13 Aug 2020 14:20:36

US3312023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:00

US3312023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:00

US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:38:40



US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:38:40

US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	Christa Estrada (b) (4)	11 Aug 2020 17:38:40

US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 17:38:40

US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	Christa Estrada (b) (4)	11 Aug 2020 17:38:40

US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '12:32'	(b) (4) Christa Estrada (b) (4)	11 Aug 2020 17:38:40

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:01:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered '11 Aug 2020 12:32'	System	11 Aug 2020 17:38:40

US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	11 Aug 2020 17:38:40

US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'ONCE'	System	11 Aug 2020 17:38:40



US3312023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 17:38:40

US3312023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:21:19

US3312023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:19

US3312023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11:33'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:19

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered '11 Aug 2020 11:33'	System	13 Aug 2020 14:21:19

US3312023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:01:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:54

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:54

US3312023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:54



US3312023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11:08'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:54

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered '11 Aug 2020 11:08'	System	13 Aug 2020 14:21:54

US3312023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:54

US3312023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:54

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:01:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:21:54

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered empty.	System	13 Aug 2020 14:21:54

US3312023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:21:58

**US3312023**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'I'	System	13 Aug 2020 14:21:58



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:05', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '6b098bd5-74f7-4ef1-b38e-15e99eb552ac'	System	11 Aug 2020 18:10:33
User entered 'Yes (Y)'	System	11 Aug 2020 18:10:33

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:19', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '6b098bd5-74f7-4ef1-b38e-15e99eb552ac'	System	11 Aug 2020 18:10:33
User entered '97.6'	System	11 Aug 2020 18:10:33

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '6b098bd5-74f7-4ef1-b38e-15e99eb552ac'	System	11 Aug 2020 18:10:33
User entered 'No (N)'	System	11 Aug 2020 18:10:33

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '6b098bd5-74f7-4ef1-b38e-15e99eb552ac'	System	11 Aug 2020 18:10:33
User entered '11 Aug 2020 13:10'	System	11 Aug 2020 18:10:33

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 12:52'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 15:22'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:38:40



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T17:59:35', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7991c4f5-376f-444b-af84-9a32925c85ae'	System	11 Aug 2020 22:59:54
User entered 'Yes (Y)'	System	11 Aug 2020 22:59:54

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T17:59:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7991c4f5-376f-444b-af84-9a32925c85ae'	System	11 Aug 2020 22:59:54
User entered '97.2'	System	11 Aug 2020 22:59:54

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T17:59:48', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7991c4f5-376f-444b-af84-9a32925c85ae'	System	11 Aug 2020 22:59:54
User entered 'No (N)'	System	11 Aug 2020 22:59:54

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T17:59:52', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7991c4f5-376f-444b-af84-9a32925c85ae'	System	11 Aug 2020 22:59:54
User entered '11 Aug 2020 17:59'	System	11 Aug 2020 22:59:54

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 16:17'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 2'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:13:53', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4a8a3dd5-908d-4b38-b531-7fba08c61539'	System	12 Aug 2020 23:14:42
User entered 'Yes (Y)'	System	12 Aug 2020 23:14:42



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:14:31', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4a8a3dd5-908d-4b38-b531-7fba08c61539'	System	12 Aug 2020 23:14:42
User entered '97.1'	System	12 Aug 2020 23:14:42

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:14:36', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4a8a3dd5-908d-4b38-b531-7fba08c61539'	System	12 Aug 2020 23:14:42
User entered 'No (N)'	System	12 Aug 2020 23:14:42

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:14:40', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4a8a3dd5-908d-4b38-b531-7fba08c61539'	System	12 Aug 2020 23:14:42
User entered '12 Aug 2020 18:14'	System	12 Aug 2020 23:14:42

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 3'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:26:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '06806d3f-805d-41af-8f09-971837d49db0'	System	13 Aug 2020 22:26:42
User entered 'Yes (Y)'	System	13 Aug 2020 22:26:42

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:26:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '06806d3f-805d-41af-8f09-971837d49db0'	System	13 Aug 2020 22:26:42
User entered '97.4'	System	13 Aug 2020 22:26:42



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:26:35', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '06806d3f-805d-41af-8f09-971837d49db0'	System	13 Aug 2020 22:26:42
User entered 'No (N)'	System	13 Aug 2020 22:26:42

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:26:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '06806d3f-805d-41af-8f09-971837d49db0'	System	13 Aug 2020 22:26:42
User entered '13 Aug 2020 17:26'	System	13 Aug 2020 22:26:42

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 4'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:42:27', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '398db1aa-9d58-4554-a131-5268449103eb'	System	14 Aug 2020 22:42:48
User entered 'Yes (Y)'	System	14 Aug 2020 22:42:48

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:42:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '398db1aa-9d58-4554-a131-5268449103eb'	System	14 Aug 2020 22:42:48
User entered '97.6'	System	14 Aug 2020 22:42:48

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:42:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '398db1aa-9d58-4554-a131-5268449103eb'	System	14 Aug 2020 22:42:48
User entered 'No (N)'	System	14 Aug 2020 22:42:48



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:42:43', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '398db1aa-9d58-4554-a131-5268449103eb'	System	14 Aug 2020 22:42:48
User entered '14 Aug 2020 17:42'	System	14 Aug 2020 22:42:48

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 5'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:23:49', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '43a95490-8bf8-4c47-9342-94bb970c4ccb'	System	15 Aug 2020 22:24:19
User entered 'Yes (Y)'	System	15 Aug 2020 22:24:19

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:23:55', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '43a95490-8bf8-4c47-9342-94bb970c4ccb'	System	15 Aug 2020 22:24:19
User entered '97.4'	System	15 Aug 2020 22:24:19

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:01', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '43a95490-8bf8-4c47-9342-94bb970c4ccb'	System	15 Aug 2020 22:24:19
User entered 'Yes (Y)'	System	15 Aug 2020 22:24:19

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
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 'CONTACT CONFIRMED. SUBJECT TOOK MEDICATION FOR AE. LISTED ON AE LOG AND CONCOMITANT MEDICATION LOG' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 16:58:04
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).	Karol Moore (b) (4)	27 Aug 2020 21:13:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '43a95490-8bf8-4c47-9342-94bb970c4ccb'	(b) (4)	
User entered '1'	System	15 Aug 2020 22:24:19
	System	15 Aug 2020 22:24:19
	System	15 Aug 2020 22:24:19



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '43a95490-8bf8-4c47-9342-94bb970c4ccb'	System	15 Aug 2020 22:24:19
User entered '0'	System	15 Aug 2020 22:24:19

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:16', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '43a95490-8bf8-4c47-9342-94bb970c4ccb'	System	15 Aug 2020 22:24:19
User entered '15 Aug 2020 17:24'	System	15 Aug 2020 22:24:19

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 6'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:49:40', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d7bc601-94ed-49c2-9454-793a302db889'	System	16 Aug 2020 21:50:14
User entered 'Yes (Y)'	System	16 Aug 2020 21:50:14

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:49:47', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d7bc601-94ed-49c2-9454-793a302db889'	System	16 Aug 2020 21:50:14
User entered '97.3'	System	16 Aug 2020 21:50:14

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:04', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d7bc601-94ed-49c2-9454-793a302db889'	System	16 Aug 2020 21:50:14
User entered 'No (N)'	System	16 Aug 2020 21:50:14



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:11', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d7bc601-94ed-49c2-9454-793a302db889'	System	16 Aug 2020 21:50:14
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 21:50:14

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 7'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:36:36', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc5f8ded-b8f4-4ee9-82a9-733f4339f42a'	System	17 Aug 2020 21:37:05
User entered 'Yes (Y)'	System	17 Aug 2020 21:37:05

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:36:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc5f8ded-b8f4-4ee9-82a9-733f4339f42a'	System	17 Aug 2020 21:37:05
User entered '97.9'	System	17 Aug 2020 21:37:05

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:36:50', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc5f8ded-b8f4-4ee9-82a9-733f4339f42a'	System	17 Aug 2020 21:37:05
User entered 'Yes (Y)'	System	17 Aug 2020 21:37:05

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
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 'CONTACT CONFIRMED. SUBJECT TOOK MEDICATION FOR AE. LISTED ON AE LOG AND CONCOMITANT MEDICATION LOG' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 16:58:15
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).	Karol Moore (b) (4)	27 Aug 2020 21:13:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:36:58', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc5f8ded-b8f4-4ee9-82a9-733f4339f42a'	(b) (4)	
User entered '1'	System	17 Aug 2020 21:37:05
	System	17 Aug 2020 21:37:05
	System	17 Aug 2020 21:37:05



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:36:58', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc5f8ded-b8f4-4ee9-82a9-733f4339f42a'	System	17 Aug 2020 21:37:05
User entered '0'	System	17 Aug 2020 21:37:05

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:02', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc5f8ded-b8f4-4ee9-82a9-733f4339f42a'	System	17 Aug 2020 21:37:05
User entered '17 Aug 2020 16:37'	System	17 Aug 2020 21:37:05

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	17 Aug 2020 21:37:05
User entered 'Day 8'	System	17 Aug 2020 21:37:05

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-18T19:20:38', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '82653e01-68b3-4d5a-a520-9a89455bc3d1'	System	19 Aug 2020 00:20:55
User entered 'Yes (Y)'	System	19 Aug 2020 00:20:55

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-18T19:20:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '82653e01-68b3-4d5a-a520-9a89455bc3d1'	System	19 Aug 2020 00:20:55
User entered '98.2'	System	19 Aug 2020 00:20:55

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-18T19:20:50', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '82653e01-68b3-4d5a-a520-9a89455bc3d1'	System	19 Aug 2020 00:20:55
User entered 'No (N)'	System	19 Aug 2020 00:20:55



US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-18T19:20:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '82653e01-68b3-4d5a-a520-9a89455bc3d1'	System	19 Aug 2020 00:20:55
User entered '18 Aug 2020 19:20'	System	19 Aug 2020 00:20:55

US3312023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 21:37:05

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 21:37:05

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:36', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa50a707-a938-4461-829e-6b961529ea41'	System	11 Aug 2020 18:10:52
User entered 'None (1)'	System	11 Aug 2020 18:10:52

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa50a707-a938-4461-829e-6b961529ea41'	System	11 Aug 2020 18:10:52
User entered 'No (N)'	System	11 Aug 2020 18:10:52

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:42', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa50a707-a938-4461-829e-6b961529ea41'	System	11 Aug 2020 18:10:52
User entered 'No (N)'	System	11 Aug 2020 18:10:52

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa50a707-a938-4461-829e-6b961529ea41'	System	11 Aug 2020 18:10:52
User entered 'None (1)'	System	11 Aug 2020 18:10:52



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:50', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa50a707-a938-4461-829e-6b961529ea41'	System	11 Aug 2020 18:10:52
User entered '11 Aug 2020 13:10'	System	11 Aug 2020 18:10:52

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 12:52'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 15:22'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:05', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '63b260d2-05e5-4de7-a17e-f8a3c00b9239'	System	11 Aug 2020 23:00:22
User entered 'None (1)'	System	11 Aug 2020 23:00:22

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:08', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '63b260d2-05e5-4de7-a17e-f8a3c00b9239'	System	11 Aug 2020 23:00:22
User entered 'No (N)'	System	11 Aug 2020 23:00:22

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '63b260d2-05e5-4de7-a17e-f8a3c00b9239'	System	11 Aug 2020 23:00:22
User entered 'No (N)'	System	11 Aug 2020 23:00:22

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '63b260d2-05e5-4de7-a17e-f8a3c00b9239'	System	11 Aug 2020 23:00:22
User entered 'None (1)'	System	11 Aug 2020 23:00:22



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:19', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '63b260d2-05e5-4de7-a17e-f8a3c00b9239'	System	11 Aug 2020 23:00:22
User entered '11 Aug 2020 18:00'	System	11 Aug 2020 23:00:22

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 16:17'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 2'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:14:53', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9ea1ae94-ffe7-4241-8cf8-8ef77e3d7720'	System	12 Aug 2020 23:15:37
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 23:15:37

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:14:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9ea1ae94-ffe7-4241-8cf8-8ef77e3d7720'	System	12 Aug 2020 23:15:37
User entered 'No (N)'	System	12 Aug 2020 23:15:37

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:04', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9ea1ae94-ffe7-4241-8cf8-8ef77e3d7720'	System	12 Aug 2020 23:15:37
User entered 'Yes (Y)'	System	12 Aug 2020 23:15:37

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:16', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9ea1ae94-ffe7-4241-8cf8-8ef77e3d7720'	System	12 Aug 2020 23:15:37
User entered '6'	System	12 Aug 2020 23:15:37



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9ea1ae94-ffe7-4241-8cf8-8ef77e3d7720'	System	12 Aug 2020 23:15:37
User entered 'None (1)'	System	12 Aug 2020 23:15:37

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9ea1ae94-ffe7-4241-8cf8-8ef77e3d7720'	System	12 Aug 2020 23:15:37
User entered '12 Aug 2020 18:15'	System	12 Aug 2020 23:15:37

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 3'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:26:48', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '05704b1d-4315-4641-b985-f0a7acefc606'	System	13 Aug 2020 22:27:13
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 22:27:13

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:26:52', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '05704b1d-4315-4641-b985-f0a7acefc606'	System	13 Aug 2020 22:27:13
User entered 'No (N)'	System	13 Aug 2020 22:27:13

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:26:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '05704b1d-4315-4641-b985-f0a7acefc606'	System	13 Aug 2020 22:27:13
User entered 'Yes (Y)'	System	13 Aug 2020 22:27:13



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:02', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '05704b1d-4315-4641-b985-f0a7acefc606'	System	13 Aug 2020 22:27:13
User entered '3'	System	13 Aug 2020 22:27:13

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '05704b1d-4315-4641-b985-f0a7acefc606'	System	13 Aug 2020 22:27:13
User entered 'None (1)'	System	13 Aug 2020 22:27:13

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:10', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '05704b1d-4315-4641-b985-f0a7acefc606'	System	13 Aug 2020 22:27:13
User entered '13 Aug 2020 17:27'	System	13 Aug 2020 22:27:13

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 4'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:42:49', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc61c006-7837-457c-b600-ac601a17b91a'	System	14 Aug 2020 22:43:06
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 22:43:06

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:42:53', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc61c006-7837-457c-b600-ac601a17b91a'	System	14 Aug 2020 22:43:06
User entered 'No (N)'	System	14 Aug 2020 22:43:06



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:42:56', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc61c006-7837-457c-b600-ac601a17b91a'	System	14 Aug 2020 22:43:06
User entered 'No (N)'	System	14 Aug 2020 22:43:06

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc61c006-7837-457c-b600-ac601a17b91a'	System	14 Aug 2020 22:43:06
User entered 'None (1)'	System	14 Aug 2020 22:43:06

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:04', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cc61c006-7837-457c-b600-ac601a17b91a'	System	14 Aug 2020 22:43:06
User entered '14 Aug 2020 17:43'	System	14 Aug 2020 22:43:06

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 5'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:25', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '1dcec526-6fa3-4187-9e32-fdc423a773a1'	System	15 Aug 2020 22:24:48
User entered 'None (1)'	System	15 Aug 2020 22:24:48

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '1dcec526-6fa3-4187-9e32-fdc423a773a1'	System	15 Aug 2020 22:24:48
User entered 'No (N)'	System	15 Aug 2020 22:24:48



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '1dcec526-6fa3-4187-9e32-fdc423a773a1'	System	15 Aug 2020 22:24:48
User entered 'No (N)'	System	15 Aug 2020 22:24:48

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:38', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '1dcec526-6fa3-4187-9e32-fdc423a773a1'	System	15 Aug 2020 22:24:48
User entered 'None (1)'	System	15 Aug 2020 22:24:48

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:42', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '1dcec526-6fa3-4187-9e32-fdc423a773a1'	System	15 Aug 2020 22:24:48
User entered '15 Aug 2020 17:24'	System	15 Aug 2020 22:24:48

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 6'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:17', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3fa5de6-0cdc-4ffb-a811-4a1c40eee749'	System	16 Aug 2020 21:50:36
User entered 'None (1)'	System	16 Aug 2020 21:50:36

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:21', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3fa5de6-0cdc-4ffb-a811-4a1c40eee749'	System	16 Aug 2020 21:50:36
User entered 'No (N)'	System	16 Aug 2020 21:50:36



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3fa5de6-0cdc-4ffb-a811-4a1c40eee749'	System	16 Aug 2020 21:50:36
User entered 'No (N)'	System	16 Aug 2020 21:50:36

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:28', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3fa5de6-0cdc-4ffb-a811-4a1c40eee749'	System	16 Aug 2020 21:50:36
User entered 'None (1)'	System	16 Aug 2020 21:50:36

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3fa5de6-0cdc-4ffb-a811-4a1c40eee749'	System	16 Aug 2020 21:50:36
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 21:50:36

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 7'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:09', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '814649ca-7326-48ad-93e9-f3242a31cf9c'	System	17 Aug 2020 21:37:26
User entered 'None (1)'	System	17 Aug 2020 21:37:26

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:13', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '814649ca-7326-48ad-93e9-f3242a31cf9c'	System	17 Aug 2020 21:37:26
User entered 'No (N)'	System	17 Aug 2020 21:37:26



US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:16', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '814649ca-7326-48ad-93e9-f3242a31cf9c'	System	17 Aug 2020 21:37:26
User entered 'No (N)'	System	17 Aug 2020 21:37:26

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '814649ca-7326-48ad-93e9-f3242a31cf9c'	System	17 Aug 2020 21:37:26
User entered 'None (1)'	System	17 Aug 2020 21:37:26

US3312023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:24', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '814649ca-7326-48ad-93e9-f3242a31cf9c'	System	17 Aug 2020 21:37:26
User entered '17 Aug 2020 16:37'	System	17 Aug 2020 21:37:26

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:56', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb'	System	11 Aug 2020 18:11:19
User entered 'None (0)'	System	11 Aug 2020 18:11:19

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:10:59', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb'	System	11 Aug 2020 18:11:19
User entered 'None (0)'	System	11 Aug 2020 18:11:19



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:11:01', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb' User entered 'None (0)'	System	11 Aug 2020 18:11:19
	System	11 Aug 2020 18:11:19

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:11:03', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb'	System	11 Aug 2020 18:11:19
User entered 'None (0)'	System	11 Aug 2020 18:11:19

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:11:05', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb'	System	11 Aug 2020 18:11:19
User entered 'None (0)'	System	11 Aug 2020 18:11:19

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:11:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb'	System	11 Aug 2020 18:11:19
User entered 'None (0)'	System	11 Aug 2020 18:11:19

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:11:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb'	System	11 Aug 2020 18:11:19
User entered 'No (N)'	System	11 Aug 2020 18:11:19

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T13:11:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '60044e29-1d3d-4930-92aa-e152d1935bfb'	System	11 Aug 2020 18:11:19
User entered '11 Aug 2020 13:11'	System	11 Aug 2020 18:11:19

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 12:52'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 15:22'	System	11 Aug 2020 17:38:40



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:26', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered 'None (0)'	System	11 Aug 2020 23:01:06

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:31', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered 'None (0)'	System	11 Aug 2020 23:01:06

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered 'None (0)'	System	11 Aug 2020 23:01:06

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered 'None (0)'	System	11 Aug 2020 23:01:06

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:41', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered 'None (0)'	System	11 Aug 2020 23:01:06

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered 'None (0)'	System	11 Aug 2020 23:01:06

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:00:56', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered 'No (N)'	System	11 Aug 2020 23:01:06



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-11T18:01:01', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3561e437-84a1-407a-bfe8-7b3ae0838dd3'	System	11 Aug 2020 23:01:06
User entered '11 Aug 2020 18:01'	System	11 Aug 2020 23:01:06

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Aug 2020 16:17'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 2'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered 'None (0)'	System	12 Aug 2020 23:16:17

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:43', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered 'None (0)'	System	12 Aug 2020 23:16:17

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered 'None (0)'	System	12 Aug 2020 23:16:17

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:48', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered 'None (0)'	System	12 Aug 2020 23:16:17



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:15:58', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered 'None (0)'	System	12 Aug 2020 23:16:17

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:16:01', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered 'None (0)'	System	12 Aug 2020 23:16:17

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:16:04', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered 'No (N)'	System	12 Aug 2020 23:16:17

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-12T18:16:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '15e796ee-dad0-470e-b668-4e46a52914b7'	System	12 Aug 2020 23:16:17
User entered '12 Aug 2020 18:16'	System	12 Aug 2020 23:16:17

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 3'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered 'None (0)'	System	13 Aug 2020 22:27:41



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:18', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered 'None (0)'	System	13 Aug 2020 22:27:41

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:21', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered 'None (0)'	System	13 Aug 2020 22:27:41

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered 'None (0)'	System	13 Aug 2020 22:27:41

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:25', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered 'None (0)'	System	13 Aug 2020 22:27:41

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:28', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered 'None (0)'	System	13 Aug 2020 22:27:41

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:35', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered 'No (N)'	System	13 Aug 2020 22:27:41

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-13T17:27:38', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '11c6580f-b486-4e9b-9cbc-5a9bc6068411'	System	13 Aug 2020 22:27:41
User entered '13 Aug 2020 17:27'	System	13 Aug 2020 22:27:41

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:38:40



**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 4'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:10', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered 'None (0)'	System	14 Aug 2020 22:43:36

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered 'None (0)'	System	14 Aug 2020 22:43:36

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered 'None (0)'	System	14 Aug 2020 22:43:36

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:18', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered 'None (0)'	System	14 Aug 2020 22:43:36

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered 'None (0)'	System	14 Aug 2020 22:43:36

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered 'None (0)'	System	14 Aug 2020 22:43:36



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered 'No (N)'	System	14 Aug 2020 22:43:36

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-14T17:43:32', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e3c2e5e9-956e-41d3-a23c-6d826e6055c3'	System	14 Aug 2020 22:43:36
User entered '14 Aug 2020 17:43'	System	14 Aug 2020 22:43:36

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 5'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:49', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered 'None (0)'	System	15 Aug 2020 22:25:29

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:53', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered 'None (0)'	System	15 Aug 2020 22:25:29

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:24:58', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered 'None (0)'	System	15 Aug 2020 22:25:29



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:25:03', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered 'None (0)'	System	15 Aug 2020 22:25:29

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:25:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered 'None (0)'	System	15 Aug 2020 22:25:29

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:25:11', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered 'None (0)'	System	15 Aug 2020 22:25:29

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:25:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered 'Yes (Y)'	System	15 Aug 2020 22:25:29

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-15T17:25:26', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '31bf4676-a09d-4d2e-94d3-b1c38c16efca'	System	15 Aug 2020 22:25:29
User entered '15 Aug 2020 17:25'	System	15 Aug 2020 22:25:29

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 6'	System	11 Aug 2020 17:38:40



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:50:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered 'None (0)'	System	16 Aug 2020 21:51:31

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:51:03', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered 'None (0)'	System	16 Aug 2020 21:51:31

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:51:06', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered 'None (0)'	System	16 Aug 2020 21:51:31

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:51:09', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered 'None (0)'	System	16 Aug 2020 21:51:31

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:51:11', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered 'None (0)'	System	16 Aug 2020 21:51:31

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:51:17', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered 'None (0)'	System	16 Aug 2020 21:51:31

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:51:25', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered 'Yes (Y)'	System	16 Aug 2020 21:51:31

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-16T16:51:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aa219c71-6438-4621-a8a5-a1d94a5247ae'	System	16 Aug 2020 21:51:31
User entered '16 Aug 2020 16:51'	System	16 Aug 2020 21:51:31



**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 7'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:37', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered 'None (0)'	System	17 Aug 2020 21:38:20

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:46', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered 'None (0)'	System	17 Aug 2020 21:38:20

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:51', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered 'None (0)'	System	17 Aug 2020 21:38:20

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:37:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered 'None (0)'	System	17 Aug 2020 21:38:20

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:38:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered 'None (0)'	System	17 Aug 2020 21:38:20



US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:38:03', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered 'None (0)'	System	17 Aug 2020 21:38:20

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:38:11', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered 'Yes (Y)'	System	17 Aug 2020 21:38:20

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-17T16:38:16', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '70cab07a-22a8-49ff-9ab7-b65893dc0ee2'	System	17 Aug 2020 21:38:20
User entered '17 Aug 2020 16:38'	System	17 Aug 2020 21:38:20

US3312023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	17 Aug 2020 21:37:05
User entered 'Day 8'	System	17 Aug 2020 21:37:05

US3312023

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-18T19:21:04', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '82300c75-9e4a-409f-9670-069ab80e958c'	System	19 Aug 2020 00:21:10
User entered 'No (N)'	System	19 Aug 2020 00:21:10

US3312023

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-08-18T19:21:08', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '82300c75-9e4a-409f-9670-069ab80e958c'	System	19 Aug 2020 00:21:10
User entered '18 Aug 2020 19:21'	System	19 Aug 2020 00:21:10



**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 21:37:05

**US3312023**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 21:37:05

**US3312023**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:16:25

**US3312023**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '18 Aug 2020'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:16:25

US3312023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:16:25

US3312023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:16:25

US3312023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:16:30

**US3312023**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'I'	System	18 Aug 2020 20:16:30



**US3312023**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:45:49

US3312023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '25 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:45:49

US3312023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:45:49

US3312023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4)	26 Aug 2020 14:45:49
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:45:53

**US3312023**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:52:12
User entered 'I'	System	26 Aug 2020 14:45:53

**US3312023**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 13:45:42

US3312023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '1 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 13:45:42



US3312023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 13:45:42

US3312023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 13:45:42

US3312023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 13:45:46

**US3312023**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:03
User entered 'I'	System	02 Sep 2020 13:45:46

**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 15:49:56

**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '8 Sep 2020'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 15:49:56

US3312023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	08 Sep 2020 15:49:56

**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'VISIT2'	System	08 Sep 2020 15:49:56



US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '09:34'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered '08 Sep 2020 09:34'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '97.8' F	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:47



US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '78'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'bpm'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '12'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'breaths/min'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '130'	(b) (4)	11 Sep 2020 16:19:47
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'mmHg'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '72'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'mmHg'	System	11 Sep 2020 16:19:47



US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '11:17'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered '08 Sep 2020 11:17'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '98.0' F	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:47



US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '69'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'bpm'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '14'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'breaths/min'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '136'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'mmHg'	System	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '75'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:47

US3312023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'mmHg'	System	11 Sep 2020 16:19:47



US3312023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:19:54

US3312023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:19:54

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '8 Sep 2020'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '10:46'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 15:50:18



US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered '8 Sep 2020 10:46'	System	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'ONCE'	System	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:50:18

US3312023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:20:08

US3312023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:20:08

US3312023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '10:09'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:20:08

**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered '08 Sep 2020 10:09'	System	11 Sep 2020 16:20:08



US3312023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:01:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:20:20

US3312023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:20:20

US3312023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:20:20

**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:01:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '09:52'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:20:20

**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered '08 Sep 2020 09:52'	System	11 Sep 2020 16:20:20

US3312023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:20:20

US3312023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	11 Sep 2020 16:20:20

US3312023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 16:20:20



**US3312023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered empty.	System	11 Sep 2020 16:20:20

US3312023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 15:50:52

US3312023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'I'	System	08 Sep 2020 15:50:52

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:18:50', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aee942a5-5e54-452d-9e0a-7e89e4cffc9d'	System	08 Sep 2020 16:19:15
User entered 'Yes (Y)'	System	08 Sep 2020 16:19:15

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:18:58', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aee942a5-5e54-452d-9e0a-7e89e4cffc9d'	System	08 Sep 2020 16:19:15
User entered '98.0'	System	08 Sep 2020 16:19:15

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:06', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aee942a5-5e54-452d-9e0a-7e89e4cffc9d'	System	08 Sep 2020 16:19:15
User entered 'No (N)'	System	08 Sep 2020 16:19:15

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:13', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aee942a5-5e54-452d-9e0a-7e89e4cffc9d'	System	08 Sep 2020 16:19:15
User entered '08 Sep 2020 11:19'	System	08 Sep 2020 16:19:15



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 11:06'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 13:36'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:17:31', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '257b3fdb-d409-4e71-94ac-138d190bee64'	System	08 Sep 2020 22:18:14
User entered 'Yes (Y)'	System	08 Sep 2020 22:18:14

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:02', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '257b3fdb-d409-4e71-94ac-138d190bee64'	System	08 Sep 2020 22:18:14
User entered '97.9'	System	08 Sep 2020 22:18:14

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '257b3fdb-d409-4e71-94ac-138d190bee64'	System	08 Sep 2020 22:18:14
User entered 'No (N)'	System	08 Sep 2020 22:18:14

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:10', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '257b3fdb-d409-4e71-94ac-138d190bee64'	System	08 Sep 2020 22:18:14
User entered '08 Sep 2020 17:18'	System	08 Sep 2020 22:18:14

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 14:31'	System	08 Sep 2020 15:50:18



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 2'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:40:01', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '66f69df9-6b78-4fc5-81dc-78aa039176e3'	System	09 Sep 2020 23:40:25
User entered 'Yes (Y)'	System	09 Sep 2020 23:40:25

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:40:10', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '66f69df9-6b78-4fc5-81dc-78aa039176e3'	System	09 Sep 2020 23:40:25
User entered '97.8'	System	09 Sep 2020 23:40:25

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:40:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '66f69df9-6b78-4fc5-81dc-78aa039176e3'	System	09 Sep 2020 23:40:25
User entered 'No (N)'	System	09 Sep 2020 23:40:25

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:40:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '66f69df9-6b78-4fc5-81dc-78aa039176e3'	System	09 Sep 2020 23:40:25
User entered '09 Sep 2020 18:40'	System	09 Sep 2020 23:40:25

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:50:18



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 3'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:48:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7008f5cf-69d2-4b50-b026-aed304cf0f3d'	System	11 Sep 2020 00:49:22
User entered 'Yes (Y)'	System	11 Sep 2020 00:49:22

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:49:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7008f5cf-69d2-4b50-b026-aed304cf0f3d'	System	11 Sep 2020 00:49:22
User entered '97.8'	System	11 Sep 2020 00:49:22

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:49:17', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7008f5cf-69d2-4b50-b026-aed304cf0f3d'	System	11 Sep 2020 00:49:22
User entered 'No (N)'	System	11 Sep 2020 00:49:22

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:49:21', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '7008f5cf-69d2-4b50-b026-aed304cf0f3d'	System	11 Sep 2020 00:49:22
User entered '10 Sep 2020 19:49'	System	11 Sep 2020 00:49:22

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 4'	System	08 Sep 2020 15:50:18



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:30:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '81509a98-b041-4937-b7c9-1e5c424febed'	System	11 Sep 2020 21:31:16
User entered 'Yes (Y)'	System	11 Sep 2020 21:31:16

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:30:48', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '81509a98-b041-4937-b7c9-1e5c424febed'	System	11 Sep 2020 21:31:16
User entered '98.4'	System	11 Sep 2020 21:31:16

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:30:52', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '81509a98-b041-4937-b7c9-1e5c424febed'	System	11 Sep 2020 21:31:16
User entered 'No (N)'	System	11 Sep 2020 21:31:16

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:30:56', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '81509a98-b041-4937-b7c9-1e5c424febed'	System	11 Sep 2020 21:31:16
User entered '11 Sep 2020 16:30'	System	11 Sep 2020 21:31:16

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 5'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:22:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '387ce933-2b87-49a0-9cdf-8834a93f6d80'	System	12 Sep 2020 20:23:06
User entered 'Yes (Y)'	System	12 Sep 2020 20:23:06



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:22:52', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '387ce933-2b87-49a0-9cdf-8834a93f6d80'	System	12 Sep 2020 20:23:06
User entered '97.7'	System	12 Sep 2020 20:23:06

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:22:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '387ce933-2b87-49a0-9cdf-8834a93f6d80'	System	12 Sep 2020 20:23:06
User entered 'No (N)'	System	12 Sep 2020 20:23:06

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:02', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '387ce933-2b87-49a0-9cdf-8834a93f6d80'	System	12 Sep 2020 20:23:06
User entered '12 Sep 2020 15:23'	System	12 Sep 2020 20:23:06

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 6'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ec65cf2e-9ca2-4d4e-9741-77c095166298'	System	13 Sep 2020 21:13:33
User entered 'Yes (Y)'	System	13 Sep 2020 21:13:33

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:18', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ec65cf2e-9ca2-4d4e-9741-77c095166298'	System	13 Sep 2020 21:13:33
User entered '98.2'	System	13 Sep 2020 21:13:33



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ec65cf2e-9ca2-4d4e-9741-77c095166298'	System	13 Sep 2020 21:13:33
User entered 'No (N)'	System	13 Sep 2020 21:13:33

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:28', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ec65cf2e-9ca2-4d4e-9741-77c095166298'	System	13 Sep 2020 21:13:33
User entered '13 Sep 2020 16:13'	System	13 Sep 2020 21:13:33

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 7'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:57:31', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'a2f7a382-4eb1-4dbb-b712-577eeb20a676'	System	14 Sep 2020 21:57:47
User entered 'Yes (Y)'	System	14 Sep 2020 21:57:47

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:57:37', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'a2f7a382-4eb1-4dbb-b712-577eeb20a676'	System	14 Sep 2020 21:57:47
User entered '97.9'	System	14 Sep 2020 21:57:47

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:57:41', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'a2f7a382-4eb1-4dbb-b712-577eeb20a676'	System	14 Sep 2020 21:57:47
User entered 'No (N)'	System	14 Sep 2020 21:57:47



US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:57:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'a2f7a382-4eb1-4dbb-b712-577eeb20a676'	System	14 Sep 2020 21:57:47
User entered '14 Sep 2020 16:57'	System	14 Sep 2020 21:57:47

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:21', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ee66f212-1c95-4c54-ae0-b5ff109774dc'	System	08 Sep 2020 16:19:41
User entered 'None (1)'	System	08 Sep 2020 16:19:41

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:27', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ee66f212-1c95-4c54-ae0-b5ff109774dc'	System	08 Sep 2020 16:19:41
User entered 'No (N)'	System	08 Sep 2020 16:19:41

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:31', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ee66f212-1c95-4c54-ae0-b5ff109774dc'	System	08 Sep 2020 16:19:41
User entered 'No (N)'	System	08 Sep 2020 16:19:41

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ee66f212-1c95-4c54-ae0-b5ff109774dc'	System	08 Sep 2020 16:19:41
User entered 'None (1)'	System	08 Sep 2020 16:19:41



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:38', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ee66f212-1c95-4c54-ae0-b5ff109774dc'	System	08 Sep 2020 16:19:41
User entered '08 Sep 2020 11:19'	System	08 Sep 2020 16:19:41

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 11:06'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 13:36'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:17', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d27c337-e271-4717-880d-c67c6122b441'	System	08 Sep 2020 22:18:34
User entered 'None (1)'	System	08 Sep 2020 22:18:34

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:21', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d27c337-e271-4717-880d-c67c6122b441'	System	08 Sep 2020 22:18:34
User entered 'No (N)'	System	08 Sep 2020 22:18:34

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:24', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d27c337-e271-4717-880d-c67c6122b441'	System	08 Sep 2020 22:18:34
User entered 'No (N)'	System	08 Sep 2020 22:18:34

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d27c337-e271-4717-880d-c67c6122b441'	System	08 Sep 2020 22:18:34
User entered 'None (1)'	System	08 Sep 2020 22:18:34



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:32', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8d27c337-e271-4717-880d-c67c6122b441'	System	08 Sep 2020 22:18:34
User entered '08 Sep 2020 17:18'	System	08 Sep 2020 22:18:34

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 14:31'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 2'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:40:32', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '5e890327-7b36-4e0c-86a8-a56959ac62a0'	System	09 Sep 2020 23:41:12
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 23:41:12

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:40:36', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '5e890327-7b36-4e0c-86a8-a56959ac62a0'	System	09 Sep 2020 23:41:12
User entered 'No (N)'	System	09 Sep 2020 23:41:12

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:40:46', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '5e890327-7b36-4e0c-86a8-a56959ac62a0'	System	09 Sep 2020 23:41:12
User entered 'Yes (Y)'	System	09 Sep 2020 23:41:12

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:01', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '5e890327-7b36-4e0c-86a8-a56959ac62a0'	System	09 Sep 2020 23:41:12
User entered '50'	System	09 Sep 2020 23:41:12



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '5e890327-7b36-4e0c-86a8-a56959ac62a0'	System	09 Sep 2020 23:41:12
User entered 'None (1)'	System	09 Sep 2020 23:41:12

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:11', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '5e890327-7b36-4e0c-86a8-a56959ac62a0'	System	09 Sep 2020 23:41:12
User entered '09 Sep 2020 18:41'	System	09 Sep 2020 23:41:12

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 3'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:49:32', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '076da345-9068-41cc-adcf-825b86f2fb11'	System	11 Sep 2020 00:50:17
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 00:50:17

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:49:37', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '076da345-9068-41cc-adcf-825b86f2fb11'	System	11 Sep 2020 00:50:17
User entered 'No (N)'	System	11 Sep 2020 00:50:17

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:49:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '076da345-9068-41cc-adcf-825b86f2fb11'	System	11 Sep 2020 00:50:17
User entered 'Yes (Y)'	System	11 Sep 2020 00:50:17



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '076da345-9068-41cc-adcf-825b86f2fb11'	System	11 Sep 2020 00:50:17
User entered '42'	System	11 Sep 2020 00:50:17

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:12', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '076da345-9068-41cc-adcf-825b86f2fb11'	System	11 Sep 2020 00:50:17
User entered 'None (1)'	System	11 Sep 2020 00:50:17

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '076da345-9068-41cc-adcf-825b86f2fb11'	System	11 Sep 2020 00:50:17
User entered '10 Sep 2020 19:50'	System	11 Sep 2020 00:50:17

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 4'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:09', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'caf4cf24-0d64-4298-8fca-ea9b78b63947'	System	11 Sep 2020 21:31:49
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 21:31:49

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'caf4cf24-0d64-4298-8fca-ea9b78b63947'	System	11 Sep 2020 21:31:49
User entered 'No (N)'	System	11 Sep 2020 21:31:49



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:26', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'caf4cf24-0d64-4298-8fca-ea9b78b63947'	System	11 Sep 2020 21:31:49
User entered 'Yes (Y)'	System	11 Sep 2020 21:31:49

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'caf4cf24-0d64-4298-8fca-ea9b78b63947'	System	11 Sep 2020 21:31:49
User entered '40'	System	11 Sep 2020 21:31:49

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'caf4cf24-0d64-4298-8fca-ea9b78b63947'	System	11 Sep 2020 21:31:49
User entered 'None (1)'	System	11 Sep 2020 21:31:49

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:47', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'caf4cf24-0d64-4298-8fca-ea9b78b63947'	System	11 Sep 2020 21:31:49
User entered '11 Sep 2020 16:31'	System	11 Sep 2020 21:31:49

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 5'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:11', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3d189ab6-6229-439a-8c95-2d150b8b4b05'	System	12 Sep 2020 20:23:30
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 20:23:30



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3d189ab6-6229-439a-8c95-2d150b8b4b05'	System	12 Sep 2020 20:23:30
User entered 'No (N)'	System	12 Sep 2020 20:23:30

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:19', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3d189ab6-6229-439a-8c95-2d150b8b4b05'	System	12 Sep 2020 20:23:30
User entered 'No (N)'	System	12 Sep 2020 20:23:30

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3d189ab6-6229-439a-8c95-2d150b8b4b05'	System	12 Sep 2020 20:23:30
User entered 'None (1)'	System	12 Sep 2020 20:23:30

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:27', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3d189ab6-6229-439a-8c95-2d150b8b4b05'	System	12 Sep 2020 20:23:30
User entered '12 Sep 2020 15:23'	System	12 Sep 2020 20:23:30

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 6'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:37', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '562f7ed2-f1df-470a-a65c-50c64f25679d'	System	13 Sep 2020 21:13:59
User entered 'None (1)'	System	13 Sep 2020 21:13:59



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:42', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '562f7ed2-f1df-470a-a65c-50c64f25679d'	System	13 Sep 2020 21:13:59
User entered 'No (N)'	System	13 Sep 2020 21:13:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '562f7ed2-f1df-470a-a65c-50c64f25679d'	System	13 Sep 2020 21:13:59
User entered 'No (N)'	System	13 Sep 2020 21:13:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:51', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '562f7ed2-f1df-470a-a65c-50c64f25679d'	System	13 Sep 2020 21:13:59
User entered 'None (1)'	System	13 Sep 2020 21:13:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:13:55', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '562f7ed2-f1df-470a-a65c-50c64f25679d'	System	13 Sep 2020 21:13:59
User entered '13 Sep 2020 16:13'	System	13 Sep 2020 21:13:59

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 7'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:57:51', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ed7ea596-5a6f-483d-ac61-690bff47a3ce'	System	14 Sep 2020 21:58:13
User entered 'None (1)'	System	14 Sep 2020 21:58:13



US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:57:55', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ed7ea596-5a6f-483d-ac61-690bff47a3ce'	System	14 Sep 2020 21:58:13
User entered 'No (N)'	System	14 Sep 2020 21:58:13

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:57:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ed7ea596-5a6f-483d-ac61-690bff47a3ce'	System	14 Sep 2020 21:58:13
User entered 'No (N)'	System	14 Sep 2020 21:58:13

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:01', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ed7ea596-5a6f-483d-ac61-690bff47a3ce'	System	14 Sep 2020 21:58:13
User entered 'None (1)'	System	14 Sep 2020 21:58:13

US3312023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:08', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'ed7ea596-5a6f-483d-ac61-690bff47a3ce'	System	14 Sep 2020 21:58:13
User entered '14 Sep 2020 16:58'	System	14 Sep 2020 21:58:13

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered 'None (0)'	System	08 Sep 2020 16:20:11



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:48', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered 'None (0)'	System	08 Sep 2020 16:20:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:50', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered 'None (0)'	System	08 Sep 2020 16:20:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:52', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered 'None (0)'	System	08 Sep 2020 16:20:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered 'None (0)'	System	08 Sep 2020 16:20:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:19:56', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered 'None (0)'	System	08 Sep 2020 16:20:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:20:04', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered 'No (N)'	System	08 Sep 2020 16:20:11

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T11:20:06', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cf444b0d-d1d3-45cb-8ba7-99fdbecb1e77'	System	08 Sep 2020 16:20:11
User entered '08 Sep 2020 11:20'	System	08 Sep 2020 16:20:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 11:06'	System	08 Sep 2020 15:50:18



**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 13:36'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:38', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered 'None (0)'	System	08 Sep 2020 22:19:01

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:41', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered 'None (0)'	System	08 Sep 2020 22:19:01

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered 'None (0)'	System	08 Sep 2020 22:19:01

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:46', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered 'None (0)'	System	08 Sep 2020 22:19:01

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:49', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered 'None (0)'	System	08 Sep 2020 22:19:01

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:51', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered 'None (0)'	System	08 Sep 2020 22:19:01



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:56', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered 'No (N)'	System	08 Sep 2020 22:19:01

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-08T17:18:59', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '42fd338b-7a85-42e0-84c2-6df4ae01377d'	System	08 Sep 2020 22:19:01
User entered '08 Sep 2020 17:18'	System	08 Sep 2020 22:19:01

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '08 Sep 2020 14:31'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:01:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 2'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:18', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered 'None (0)'	System	09 Sep 2020 23:41:48

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered 'None (0)'	System	09 Sep 2020 23:41:48

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:26', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered 'None (0)'	System	09 Sep 2020 23:41:48



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:31', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered 'None (0)'	System	09 Sep 2020 23:41:48

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered 'None (0)'	System	09 Sep 2020 23:41:48

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:38', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered 'None (0)'	System	09 Sep 2020 23:41:48

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:43', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered 'No (N)'	System	09 Sep 2020 23:41:48

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-09T18:41:46', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '25c636fd-4ba5-462e-932d-00f5bd0055d8'	System	09 Sep 2020 23:41:48
User entered '09 Sep 2020 18:41'	System	09 Sep 2020 23:41:48

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 3'	System	08 Sep 2020 15:50:18



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered 'None (0)'	System	11 Sep 2020 00:50:47

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:24', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered 'None (0)'	System	11 Sep 2020 00:50:47

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:27', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered 'None (0)'	System	11 Sep 2020 00:50:47

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:30', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered 'None (0)'	System	11 Sep 2020 00:50:47

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:33', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered 'None (0)'	System	11 Sep 2020 00:50:47

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:36', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered 'None (0)'	System	11 Sep 2020 00:50:47

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:41', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered 'No (N)'	System	11 Sep 2020 00:50:47

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-10T19:50:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '968b9a0c-3cd8-4549-a49e-0a0d176ad1db'	System	11 Sep 2020 00:50:47
User entered '10 Sep 2020 19:50'	System	11 Sep 2020 00:50:47



**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 4'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered 'None (0)'	System	11 Sep 2020 21:32:29

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:31:58', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered 'None (0)'	System	11 Sep 2020 21:32:29

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:32:02', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered 'None (0)'	System	11 Sep 2020 21:32:29

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:32:06', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered 'None (0)'	System	11 Sep 2020 21:32:29

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:32:11', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered 'None (0)'	System	11 Sep 2020 21:32:29



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:32:15', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered 'None (0)'	System	11 Sep 2020 21:32:29

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:32:22', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered 'No (N)'	System	11 Sep 2020 21:32:29

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-11T16:32:26', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'fe8d2f72-c792-47cf-9adb-611f7a790f6a'	System	11 Sep 2020 21:32:29
User entered '11 Sep 2020 16:32'	System	11 Sep 2020 21:32:29

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 5'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered 'None (0)'	System	12 Sep 2020 20:24:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:42', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered 'No interference with activity (1)'	System	12 Sep 2020 20:24:11



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:46', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered 'None (0)'	System	12 Sep 2020 20:24:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:51', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered 'None (0)'	System	12 Sep 2020 20:24:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered 'None (0)'	System	12 Sep 2020 20:24:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:23:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered 'None (0)'	System	12 Sep 2020 20:24:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:24:02', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered 'No (N)'	System	12 Sep 2020 20:24:11

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-12T15:24:05', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f6b4b2a5-6978-41f2-a372-e2d8843c4b1e'	System	12 Sep 2020 20:24:11
User entered '12 Sep 2020 15:24'	System	12 Sep 2020 20:24:11

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:50:18



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 6'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:02', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered 'None (0)'	System	13 Sep 2020 21:14:35

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:07', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered 'No interference with activity (1)'	System	13 Sep 2020 21:14:35

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:13', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered 'None (0)'	System	13 Sep 2020 21:14:35

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:16', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered 'None (0)'	System	13 Sep 2020 21:14:35

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered 'None (0)'	System	13 Sep 2020 21:14:35

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:24', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered 'None (0)'	System	13 Sep 2020 21:14:35

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered 'No (N)'	System	13 Sep 2020 21:14:35



**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-13T16:14:33', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '38c408ee-e723-457c-bcb7-de6edb6dfe27'	System	13 Sep 2020 21:14:35
User entered '13 Sep 2020 16:14'	System	13 Sep 2020 21:14:35

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	08 Sep 2020 15:50:18
User entered 'Day 7'	System	08 Sep 2020 15:50:18

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:13', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered 'None (0)'	System	14 Sep 2020 21:58:46

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:17', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered 'None (0)'	System	14 Sep 2020 21:58:46

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:21', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered 'None (0)'	System	14 Sep 2020 21:58:46

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:23', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered 'None (0)'	System	14 Sep 2020 21:58:46



US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:26', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered 'None (0)'	System	14 Sep 2020 21:58:46

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:29', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered 'None (0)'	System	14 Sep 2020 21:58:46

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered 'No (N)'	System	14 Sep 2020 21:58:46

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-09-14T16:58:42', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f249481a-edc8-4d36-8c2e-e7d77b6e743b'	System	14 Sep 2020 21:58:46
User entered '14 Sep 2020 16:58'	System	14 Sep 2020 21:58:46

US3312023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:01:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:01:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:50:18

**US3312023**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	20 Sep 2020 20:44:21

**US3312023**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '15 Sep 2020'	(b) (4) Monica Atwood (b) (4)	20 Sep 2020 20:44:21



**US3312023**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	20 Sep 2020 20:44:21

US3312023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Monica Atwood (b) (4)	20 Sep 2020 20:44:21

US3312023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	20 Sep 2020 20:44:26

**US3312023**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'I'	System	20 Sep 2020 20:44:26

**US3312023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 17:40:05

**US3312023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '23 Sep 2020'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 17:40:05

US3312023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 17:40:05

US3312023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 17:40:05



US3312023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 17:40:09

**US3312023**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'I'	System	03 Nov 2020 17:40:09

**US3312023**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 18:25:23

**US3312023**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '29 Sep 2020'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 18:25:23

US3312023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 18:25:23

US3312023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	03 Nov 2020 18:25:23

US3312023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	03 Nov 2020 18:25:28

**US3312023**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'I'	System	03 Nov 2020 18:25:28



**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	03 Nov 2020 20:49:12

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 20:49:12

US3312023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 20:49:12

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'VISIT3'	System	03 Nov 2020 20:49:12

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	03 Nov 2020 20:49:37

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 20:49:37

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '09:18'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 20:49:37

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered '06 Oct 2020 09:18'	System	03 Nov 2020 20:49:37



US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '98.8' F	(b) (4)	03 Nov 2020 20:49:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 20:49:37

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	(b) (4) Karol Moore (b) (4)	03 Nov 2020 20:49:37

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '72'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 20:49:37

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'bpm'	System	03 Nov 2020 20:49:37

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 20:49:37

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'breaths/min'	System	03 Nov 2020 20:49:37

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '143' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 19:48:56
User entered '145'	Monica Atwood (b) (4)	02 Feb 2021 19:48:56
	(b) (4)	
	Karol Moore (b) (4)	03 Nov 2020 20:49:37
	(b) (4)	



**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'mmHg'	System	03 Nov 2020 20:49:37

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered '83' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 19:48:56
User entered '90'	Monica Atwood (b) (4)	02 Feb 2021 19:48:56
	(b) (4)	
	Karol Moore (b) (4)	03 Nov 2020 20:49:37
	(b) (4)	

US3312023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'mmHg'	System	03 Nov 2020 20:49:37

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06

US3312023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User closed query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM). Query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4) (b) (4), (b) (6) Karol Moore (b) (4) (b) (4)	29 Mar 2021 11:03:08 26 Mar 2021 15:48:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	26 Mar 2021 15:48:45
User opened query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM). Query 'Query issued on Visit 3 Day 57 Vital signs form: Per CDM: Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' canceled (Site from DM).	(b) (4) Karol Moore (b) (4) (b) (4) (b) (4), (b) (6)	26 Mar 2021 15:48:45 21 Mar 2021 02:18:05
User opened query 'Query issued on Visit 3 Day 57 Vital signs form: Per CDM: Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' canceled (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:17:47
User opened query 'Query issued on Visit 3 Day 57 Vital signs form: Per CDM: Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:11:19

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:01:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	03 Nov 2020 20:49:47
	(b) (4)	

US3312023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Signature has been broken.	(b) (4)	26 Mar 2021 15:48:45
User entered '06 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	26 Mar 2021 15:48:45
User signature succeeded.	(b) (4)	15 Feb 2021 21:39:34
User entered empty.	Carlos Fierro (b) (4)	03 Nov 2020 20:49:47
	(b) (4)	



US3312023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User closed query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, 'Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection' was collected for Illness Visit Day 1, but 'Immunogenicity Assessment' sample was not collected for Visit 3 Day 57. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:11:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
Query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, 'Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection' was collected for Illness Visit Day 1, but 'Immunogenicity Assessment' sample was not collected for Visit 3 Day 57. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated' (Site from DM).	(b) (4) Monica Atwood (b) (4)	07 Apr 2021 15:12:16
Signature has been broken.	Monica Atwood (b) (4)	07 Apr 2021 15:11:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Monica Atwood (b) (4)	07 Apr 2021 15:11:12
User opened query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 06Oct2020. However, 'Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection' was collected for Illness Visit Day 1, but 'Immunogenicity Assessment' sample was not collected for Visit 3 Day 57. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:13:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	03 Nov 2020 20:49:51

US3312023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06OCT2020 is recorded under Visit 03 Day 57 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:19:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06OCT2020 is recorded under Visit 03 Day 57 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' answered with 'CONFIRMED SHIPPED. ACCESSION NUMBER: 1F654785644 SHIPPING NUMBER: 1001891950910006408600771723088504' (Site from DM).	Karol Moore (b) (4) (b) (4)	15 Apr 2021 15:55:29
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06OCT2020 is recorded under Visit 03 Day 57 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 07:38:48
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:08:36
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Apr 2021 15:11:52
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		07 Apr 2021 15:11:52
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	07 Apr 2021 15:11:52
User entered '06 Oct 2020' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 15:11:52
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	07 Apr 2021 15:11:12

US3312023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Apr 2021 15:11:12
Signature has been broken.	Monica Atwood (b) (4)	07 Apr 2021 15:11:12
User entered '06 Oct 2021' reason for change: Data Entry Error	Monica Atwood (b) (4)	07 Apr 2021 15:11:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered empty.	Karol Moore (b) (4)	03 Nov 2020 20:49:51

US3312023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
Signature has been broken.	(b) (4)	07 Apr 2021 15:11:12
User entered '10:38' reason for change: Data Entry Error	Monica Atwood (b) (4)	07 Apr 2021 15:11:12
User signature succeeded.	(b) (4)	15 Feb 2021 21:39:34
User entered empty.	Karol Moore (b) (4)	03 Nov 2020 20:49:51
	(b) (4)	

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered '06 Oct 2020 10:38'	System	07 Apr 2021 15:11:52
User entered '06 Oct 2021 10:38'	System	07 Apr 2021 15:11:12
User entered empty.	System	03 Nov 2020 20:49:51

US3312023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:39:34
User entered 'Yes (Y)'	(b) (4)	03 Nov 2020 20:49:56
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'I'	System	03 Nov 2020 20:49:56

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 64'	System	11 Aug 2020 17:38:40



US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

[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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-13T16:11:41', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '33e89645-0f1a-4af2-a8b2-14a982e17fac'	System	13 Oct 2020 21:11:58
User entered 'No (N)'	System	13 Oct 2020 21:11:58

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

Have you been exposed to someone with 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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-13T16:11:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '33e89645-0f1a-4af2-a8b2-14a982e17fac'	System	13 Oct 2020 21:11:58
User entered 'No (N)'	System	13 Oct 2020 21:11:58

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-13T16:11:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '33e89645-0f1a-4af2-a8b2-14a982e17fac'	System	13 Oct 2020 21:11:58
User entered '13 Oct 2020 16:11:54'	System	13 Oct 2020 21:11:58

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 71'	System	11 Aug 2020 17:38:40

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

[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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-18T09:00:49', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '39a895f9-ff4d-4aaa-851f-112b445ef29c'	System	18 Oct 2020 14:01:05
User entered 'No (N)'	System	18 Oct 2020 14:01:05

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

Have you been exposed to someone with 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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-18T09:00:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '39a895f9-ff4d-4aaa-851f-112b445ef29c'	System	18 Oct 2020 14:01:05
User entered 'No (N)'	System	18 Oct 2020 14:01:05



**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-18T09:01:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '39a895f9-ff4d-4aaa-851f-112b445ef29c'	System	18 Oct 2020 14:01:05
User entered '18 Oct 2020 09:01:00'	System	18 Oct 2020 14:01:05

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 78'	System	11 Aug 2020 17:38:40

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

[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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-27T12:00:50', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0ed9c3c0-c0e0-4baa-aa1f-1300509df833'	System	27 Oct 2020 17:01:53
User entered 'No (N)'	System	27 Oct 2020 17:01:53

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

Have you been exposed to someone with 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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-27T12:00:54', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0ed9c3c0-c0e0-4baa-aa1f-1300509df833'	System	27 Oct 2020 17:01:53
User entered 'No (N)'	System	27 Oct 2020 17:01:53

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-10-27T12:00:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0ed9c3c0-c0e0-4baa-aa1f-1300509df833'	System	27 Oct 2020 17:01:53
User entered '27 Oct 2020 12:00:57'	System	27 Oct 2020 17:01:53

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 17:38:40



**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 92'	System	11 Aug 2020 17:38:40

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

[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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-11-11T13:02:27', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4f44ae49-3b63-4c13-959b-cee5d3cca82b'	System	11 Nov 2020 19:02:37
User entered 'No (N)'	System	11 Nov 2020 19:02:37

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

Have you been exposed to someone with 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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-11-11T13:02:32', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4f44ae49-3b63-4c13-959b-cee5d3cca82b'	System	11 Nov 2020 19:02:37
User entered 'No (N)'	System	11 Nov 2020 19:02:37

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-11-11T13:02:35', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4f44ae49-3b63-4c13-959b-cee5d3cca82b'	System	11 Nov 2020 19:02:37
User entered '11 Nov 2020 13:02:35'	System	11 Nov 2020 19:02:37

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 17:38:40

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered 'Day 99'	System	11 Aug 2020 17:38:40



US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

[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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-11-15T08:15:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0f511a57-f525-404f-adc5-bf120d330f2e'	System	15 Nov 2020 14:15:37
User entered 'No (N)'	System	15 Nov 2020 14:15:37

US3312023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:52

Have you been exposed to someone with 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 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-11-15T08:15:27', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0f511a57-f525-404f-adc5-bf120d330f2e'	System	15 Nov 2020 14:15:37
User entered 'No (N)'	System	15 Nov 2020 14:15:37

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-11-15T08:15:33', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0f511a57-f525-404f-adc5-bf120d330f2e'	System	15 Nov 2020 14:15:37
User entered '15 Nov 2020 08:15:33'	System	15 Nov 2020 14:15:37

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:10:35
Data entry locked.	System	11 Aug 2020 17:38:40
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 17:38:40

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2020-12-04T16:05:42', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f859ba16-91d1-49ad-807d-cd1dcb7bf323'	System	04 Dec 2020 22:05:54
User entered 'No (N)'	System	04 Dec 2020 22:05:54

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2020-12-04T16:05:47', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f859ba16-91d1-49ad-807d-cd1dcb7bf323'	System	04 Dec 2020 22:05:54
User entered 'No (N)'	System	04 Dec 2020 22:05:54

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-12-04T16:05:50', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f859ba16-91d1-49ad-807d-cd1dcb7bf323'	System	04 Dec 2020 22:05:54
User entered '04 Dec 2020 16:05:50'	System	04 Dec 2020 22:05:54

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2020-12-10T07:50:30', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '08f18ff3-4df1-4331-8403-6c15f5b64d9b'	System	10 Dec 2020 13:50:47
User entered 'No (N)'	System	10 Dec 2020 13:50:47

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2020-12-10T07:50:39', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '08f18ff3-4df1-4331-8403-6c15f5b64d9b'	System	10 Dec 2020 13:50:47
User entered 'No (N)'	System	10 Dec 2020 13:50:47

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-12-10T07:50:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '08f18ff3-4df1-4331-8403-6c15f5b64d9b'	System	10 Dec 2020 13:50:47
User entered '10 Dec 2020 07:50:45'	System	10 Dec 2020 13:50:47

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2020-12-17T14:23:35', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3c6752b7-bba4-4c31-90c7-fc40e0809bfe'	System	17 Dec 2020 20:24:02
User entered 'No (N)'	System	17 Dec 2020 20:24:02

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2020-12-17T14:23:52', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3c6752b7-bba4-4c31-90c7-fc40e0809bfe'	System	17 Dec 2020 20:24:02
User entered 'No (N)'	System	17 Dec 2020 20:24:02

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-12-17T14:23:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3c6752b7-bba4-4c31-90c7-fc40e0809bfe' User entered '17 Dec 2020 14:23:57'	System	17 Dec 2020 20:24:02
	System	17 Dec 2020 20:24:02

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2020-12-24T00:02:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f8103cf0-ff05-4ed0-9cce-232b8b32da40'	System	24 Dec 2020 06:03:42
User entered 'Yes (Y)'	System	24 Dec 2020 06:03:42

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2020-12-24T00:02:51', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f8103cf0-ff05-4ed0-9cce-232b8b32da40'	System	24 Dec 2020 06:03:42
User entered 'No (N)'	System	24 Dec 2020 06:03:42



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2020-12-24T00:02:59', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f8103cf0-ff05-4ed0-9cce-232b8b32da40'	System	24 Dec 2020 06:03:42
User entered 'No (N)'	System	24 Dec 2020 06:03:42

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2020-12-24T00:03:09', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f8103cf0-ff05-4ed0-9cce-232b8b32da40'	System	24 Dec 2020 06:03:42
User entered 'Yes (Y)'	System	24 Dec 2020 06:03:42

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Please 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 (c635f36c17983b9a)', Time: '2020-12-24T00:03:18', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f8103cf0-ff05-4ed0-9cce-232b8b32da40'	System	24 Dec 2020 06:03:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Dec 2020 06:03:42

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-12-24T00:03:34', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'f8103cf0-ff05-4ed0-9cce-232b8b32da40'	System	24 Dec 2020 06:03:42
User entered '24 Dec 2020 00:03:34'	System	24 Dec 2020 06:03:42

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2020-12-31T07:18:28', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '780a02cf-0f32-44a8-b9f7-5ca897b39743'	System	31 Dec 2020 13:18:46
User entered 'No (N)'	System	31 Dec 2020 13:18:46



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2020-12-31T07:18:35', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '780a02cf-0f32-44a8-b9f7-5ca897b39743'	System	31 Dec 2020 13:18:46
User entered 'No (N)'	System	31 Dec 2020 13:18:46

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2020-12-31T07:18:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '780a02cf-0f32-44a8-b9f7-5ca897b39743' User entered '31 Dec 2020 07:18:44'	System	31 Dec 2020 13:18:46
	System	31 Dec 2020 13:18:46

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-01-07T08:13:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'dc4159aa-b7ec-4dc4-977d-f994f999ee9e'	System	07 Jan 2021 14:13:08
User entered 'No (N)'	System	07 Jan 2021 14:13:08

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-01-07T08:13:03', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'dc4159aa-b7ec-4dc4-977d-f994f999ee9e'	System	07 Jan 2021 14:13:08
User entered 'No (N)'	System	07 Jan 2021 14:13:08

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-01-07T08:13:05', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'dc4159aa-b7ec-4dc4-977d-f994f999ee9e'	System	07 Jan 2021 14:13:08
User entered '07 Jan 2021 08:13:05'	System	07 Jan 2021 14:13:08



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-01-14T08:08:55', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aff2fd38-ae62-4608-acd8-93f4c1075e55'	System	14 Jan 2021 14:09:12
User entered 'No (N)'	System	14 Jan 2021 14:09:12

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-01-14T08:08:59', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aff2fd38-ae62-4608-acd8-93f4c1075e55'	System	14 Jan 2021 14:09:12
User entered 'No (N)'	System	14 Jan 2021 14:09:12

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-01-14T08:09:03', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'aff2fd38-ae62-4608-acd8-93f4c1075e55'	System	14 Jan 2021 14:09:12
User entered '14 Jan 2021 08:09:03'	System	14 Jan 2021 14:09:12

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-01-21T11:51:32', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '389d4044-7523-491b-83d8-d31d7b73dadab'	System	21 Jan 2021 17:51:41
User entered 'No (N)'	System	21 Jan 2021 17:51:41

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-01-21T11:51:35', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '389d4044-7523-491b-83d8-d31d7b73dadab'	System	21 Jan 2021 17:51:41
User entered 'No (N)'	System	21 Jan 2021 17:51:41

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-01-21T11:51:38', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '389d4044-7523-491b-83d8-d31d7b73dadab'	System	21 Jan 2021 17:51:41
User entered '21 Jan 2021 11:51:38'	System	21 Jan 2021 17:51:41

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-01-28T07:50:48', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0100a347-f21c-4d4d-aa0d-52fa3d9081a0'	System	28 Jan 2021 13:51:01
User entered 'No (N)'	System	28 Jan 2021 13:51:01



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-01-28T07:50:51', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0100a347-f21c-4d4d-aa0d-52fa3d9081a0'	System	28 Jan 2021 13:51:01
User entered 'No (N)'	System	28 Jan 2021 13:51:01

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-01-28T07:50:57', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '0100a347-f21c-4d4d-aa0d-52fa3d9081a0' User entered '28 Jan 2021 07:50:57'	System	28 Jan 2021 13:51:01

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-02-04T07:28:36', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '246ac811-d8dc-4723-9774-c885bbc0c50b'	System	04 Feb 2021 13:28:47
User entered 'No (N)'	System	04 Feb 2021 13:28:47

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-02-04T07:28:40', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '246ac811-d8dc-4723-9774-c885bbc0c50b'	System	04 Feb 2021 13:28:47
User entered 'No (N)'	System	04 Feb 2021 13:28:47

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-04T07:28:42', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '246ac811-d8dc-4723-9774-c885bbc0c50b'	System	04 Feb 2021 13:28:47
User entered '04 Feb 2021 07:28:42'	System	04 Feb 2021 13:28:47



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-02-11T09:14:16', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered 'Yes (Y)'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-02-11T09:14:20', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered 'No (N)'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-02-11T09:14:31', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered 'Yes (Y)'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d' User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d' User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '0'	System	11 Feb 2021 15:15:19



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '1'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d' User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:14:45', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '0'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Please 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 (c635f36c17983b9a)', Time: '2021-02-11T09:14:53', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 15:15:19



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-02-11T09:14:59', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered 'Yes (Y)'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Please 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 (c635f36c17983b9a)', Time: '2021-02-11T09:15:03', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-11T09:15:08', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '328b4c8f-e47f-4c87-978c-c3e06f3c8d3d'	System	11 Feb 2021 15:15:19
User entered '11 Feb 2021 09:15:08'	System	11 Feb 2021 15:15:19

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-02-18T07:34:36', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8bcda1f4-7d88-4db4-822c-1b9637de0598'	System	18 Feb 2021 13:34:47
User entered 'No (N)'	System	18 Feb 2021 13:34:47

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-02-18T07:34:41', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8bcda1f4-7d88-4db4-822c-1b9637de0598'	System	18 Feb 2021 13:34:47
User entered 'No (N)'	System	18 Feb 2021 13:34:47



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-18T07:34:44', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '8bcda1f4-7d88-4db4-822c-1b9637de0598'	System	18 Feb 2021 13:34:47
User entered '18 Feb 2021 07:34:44'	System	18 Feb 2021 13:34:47

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-02-26T13:55:36-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3ae88219-8419-4355-a9fd-947efe68c83d'	System	26 Feb 2021 19:55:46
User entered 'No (N)'	System	26 Feb 2021 19:55:46

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-02-26T13:55:39-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3ae88219-8419-4355-a9fd-947efe68c83d'	System	26 Feb 2021 19:55:46
User entered 'No (N)'	System	26 Feb 2021 19:55:46

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-02-26T13:55:41-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '3ae88219-8419-4355-a9fd-947efe68c83d'	System	26 Feb 2021 19:55:46
User entered '26 Feb 2021 13:55:41'	System	26 Feb 2021 19:55:46

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-03-05T13:53:54-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'd2cc889f-98ed-4df9-97c1-08e8dda2b3e8'	System	05 Mar 2021 19:54:07
User entered 'No (N)'	System	05 Mar 2021 19:54:07

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-03-05T13:53:57-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'd2cc889f-98ed-4df9-97c1-08e8dda2b3e8'	System	05 Mar 2021 19:54:07
User entered 'No (N)'	System	05 Mar 2021 19:54:07

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-03-05T13:54:01-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'd2cc889f-98ed-4df9-97c1-08e8dda2b3e8'	System	05 Mar 2021 19:54:07
User entered '05 Mar 2021 13:54:01'	System	05 Mar 2021 19:54:07

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-03-11T11:31:56-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '492ef9b6-4076-4280-9a70-e5d2219a11cc'	System	11 Mar 2021 17:32:08
User entered 'No (N)'	System	11 Mar 2021 17:32:08

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-03-11T11:32:00-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '492ef9b6-4076-4280-9a70-e5d2219a11cc'	System	11 Mar 2021 17:32:08
User entered 'No (N)'	System	11 Mar 2021 17:32:08

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-03-11T11:32:02-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '492ef9b6-4076-4280-9a70-e5d2219a11cc' User entered '11 Mar 2021 11:32:02'	System	11 Mar 2021 17:32:08
	System	11 Mar 2021 17:32:08

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-03-19T14:46:22-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '6f7861e2-fe9c-43a2-8f64-580adce61192'	System	19 Mar 2021 19:46:32
User entered 'No (N)'	System	19 Mar 2021 19:46:32

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-03-19T14:46:25-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '6f7861e2-fe9c-43a2-8f64-580adce61192'	System	19 Mar 2021 19:46:32
User entered 'No (N)'	System	19 Mar 2021 19:46:32



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-03-19T14:46:27-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '6f7861e2-fe9c-43a2-8f64-580adce61192'	System	19 Mar 2021 19:46:32
User entered '19 Mar 2021 14:46:27'	System	19 Mar 2021 19:46:32

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-03-25T11:50:03-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '085f0e18-4dbe-40d7-aebb-0a57c5ca9d65'	System	25 Mar 2021 16:50:16
User entered 'No (N)'	System	25 Mar 2021 16:50:16

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-03-25T11:50:09-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '085f0e18-4dbe-40d7-aebb-0a57c5ca9d65'	System	25 Mar 2021 16:50:16
User entered 'No (N)'	System	25 Mar 2021 16:50:16

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-03-25T11:50:14-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '085f0e18-4dbe-40d7-aebb-0a57c5ca9d65'	System	25 Mar 2021 16:50:16
User entered '25 Mar 2021 11:50:14'	System	25 Mar 2021 16:50:16

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-04-01T16:51:22-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9537401b-11aa-41bf-86d6-2634ea1b956b' User entered 'No (N)'	System	01 Apr 2021 21:51:33
	System	01 Apr 2021 21:51:33

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-04-01T16:51:24-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9537401b-11aa-41bf-86d6-2634ea1b956b'	System	01 Apr 2021 21:51:33
User entered 'No (N)'	System	01 Apr 2021 21:51:33

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-04-01T16:51:28-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9537401b-11aa-41bf-86d6-2634ea1b956b'	System	01 Apr 2021 21:51:33
User entered '01 Apr 2021 16:51:28'	System	01 Apr 2021 21:51:33

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-04-08T07:22:19-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cb7ae8ad-1fec-4c01-9c35-baa2b5c12e48'	System	08 Apr 2021 12:22:35
User entered 'No (N)'	System	08 Apr 2021 12:22:35

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-04-08T07:22:25-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cb7ae8ad-1fec-4c01-9c35-baa2b5c12e48'	System	08 Apr 2021 12:22:35
User entered 'No (N)'	System	08 Apr 2021 12:22:35

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-04-08T07:22:31-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'cb7ae8ad-1fec-4c01-9c35-baa2b5c12e48'	System	08 Apr 2021 12:22:35
User entered '08 Apr 2021 07:22:31'	System	08 Apr 2021 12:22:35

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-04-15T08:01:05-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4c5b71cb-c414-4930-97f0-5b2c1ae6e335'	System	15 Apr 2021 13:01:15
User entered 'No (N)'	System	15 Apr 2021 13:01:15

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-04-15T08:01:09-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4c5b71cb-c414-4930-97f0-5b2c1ae6e335'	System	15 Apr 2021 13:01:15
User entered 'No (N)'	System	15 Apr 2021 13:01:15



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-04-15T08:01:12-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '4c5b71cb-c414-4930-97f0-5b2c1ae6e335'	System	15 Apr 2021 13:01:15
User entered '15 Apr 2021 08:01:12'	System	15 Apr 2021 13:01:15

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-04-22T16:48:17-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9746573b-e2f2-468a-a41b-0f46d5405576' User entered 'No (N)'	System	22 Apr 2021 21:48:27
	System	22 Apr 2021 21:48:27

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-04-22T16:48:20-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9746573b-e2f2-468a-a41b-0f46d5405576' User entered 'No (N)'	System	22 Apr 2021 21:48:27
	System	22 Apr 2021 21:48:27

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-04-22T16:48:23-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: '9746573b-e2f2-468a-a41b-0f46d5405576' User entered '22 Apr 2021 16:48:23'	System	22 Apr 2021 21:48:27
	System	22 Apr 2021 21:48:27

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[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 (c635f36c17983b9a)', Time: '2021-04-30T16:32:25-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e0754320-0322-4d4f-a998-bd1ccf61fbaf'	System	30 Apr 2021 21:32:35
User entered 'No (N)'	System	30 Apr 2021 21:32:35

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

Have you been exposed to someone with 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 (c635f36c17983b9a)', Time: '2021-04-30T16:32:28-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e0754320-0322-4d4f-a998-bd1ccf61fbaf'	System	30 Apr 2021 21:32:35
User entered 'No (N)'	System	30 Apr 2021 21:32:35

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-04-30T16:32:31-05:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'e0754320-0322-4d4f-a998-bd1ccf61fbaf' User entered '30 Apr 2021 16:32:31'	System	30 Apr 2021 21:32:35
	System	30 Apr 2021 21:32:35

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:51:50



**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:51:50

**US3312023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:01:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:51:50
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:51:50

US3312023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:01:52

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 11:43:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-03-05T13:54:10-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'bf72aec9-a1d4-43d1-8c74-70176257f616'	System	05 Mar 2021 19:54:18
User entered 'No (N)'	System	05 Mar 2021 19:54:18

**US3312023**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:43:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c635f36c17983b9a)', Time: '2021-03-05T13:54:15-06:00', User OID: 'PatientReportedOutcome (US3312023)', ODM File OID: 'bf72aec9-a1d4-43d1-8c74-70176257f616' User entered '05 Mar 2021 13:54:15'	System	05 Mar 2021 19:54:18
	System	05 Mar 2021 19:54:18

**US3312023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	03 Nov 2020 21:04:16

**US3312023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '03 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:04:16

**US3312023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:04:16



US3312023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4)	03 Nov 2020 21:04:16
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:29:31
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 17:29:24
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:04:20

**US3312023**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:55:06
User entered 'I'	System	03 Nov 2020 21:04:20

**US3312023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:20:11

**US3312023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:20:11

**US3312023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:20:11

**US3312023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:20:11

US3312023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:20:15



**US3312023**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered 'I'	System	09 Dec 2020 17:20:15

**US3312023**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:04:07

**US3312023**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '05 Jan 2021'	Karol Moore (b) (4)	13 Jan 2021 15:04:07

**US3312023**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:04:07

US3312023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4)	13 Jan 2021 15:04:07
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:05:03

**US3312023**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered 'I'	System	13 Jan 2021 15:05:03

**US3312023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:40:57



**US3312023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:40:57

**US3312023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:40:57

**US3312023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:40:57

US3312023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:41:00

**US3312023**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered 'I'	System	23 Feb 2021 15:41:00

US3312023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:29:48

**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:29:48

US3312023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:29:48



**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered 'VISIT4'	System	10 Mar 2021 17:29:48

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered empty.	System	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47



**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered empty.	System	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered empty.	System	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered empty.	System	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:15:47

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered empty.	System	29 Mar 2021 20:15:47



US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29

US3312023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29

US3312023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:29:55

US3312023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:29:55

US3312023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:09

US3312023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:09

**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:01:52**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '09:25'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:09

**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered '05 Mar 2021 09:25'	System	10 Mar 2021 17:30:09



**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:17

**US3312023**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:05:29
User entered 'I'	System	10 Mar 2021 17:30:17

**US3312023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:13
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 16:42:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:31

**US3312023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:13
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 16:42:51
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:31

**US3312023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:13
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 16:42:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:31

**US3312023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:01:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:13
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 16:42:51
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:31

**US3312023**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:13
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 16:42:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:15:03

**US3312023**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:13
User entered 'I'	System	06 Apr 2021 15:15:03



US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:52

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 06 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:24:08
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 06 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Confirmed sample has been collected.' (Site from DM).	Karol Moore (b) (4)	02 Nov 2020 23:48:50
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 06 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:38:25
User entered '06 Oct 2020'	Karol Moore (b) (4)	28 Oct 2020 17:37:35

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:52

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '10:26' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 22:19:37
User entered '09:18'	Karol Moore (b) (4)	28 Oct 2020 17:37:35
	(b) (4)	

**US3312023**

**Folder: Covid-19 Assessment 06 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:01:52**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:24
User entered '06 Oct 2020 10:26'	System	22 Feb 2021 22:19:37
User entered '06 Oct 2020 09:18'	System	28 Oct 2020 17:37:35

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:52

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:37:35

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Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:52

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:37:35

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User entered '%'	System	18 Dec 2020 16:53:16
User entered empty.	System	28 Oct 2020 17:55:29

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:55:29

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '03 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User entered '%'	System	18 Dec 2020 16:53:16
User entered empty.	System	28 Oct 2020 17:56:08



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:56:08
	(b) (4)	

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Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:08



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Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:56:08

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '04 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User entered '%'	System	18 Dec 2020 16:53:16
User entered empty.	System	28 Oct 2020 17:56:50

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50



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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50



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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:56:50

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:56:50

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 4 (Day 4)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '05 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User entered '%'	System	18 Dec 2020 16:53:16
User entered empty.	System	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:53:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:57:20



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20



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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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Folder: Covid-19 Assessment 06 Oct 2020

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Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:57:20

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

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Form: Symptom Log (5)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22



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Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:58:22

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**Folder: Covid-19 Assessment 06 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User entered '%'	System	28 Oct 2020 17:58:22

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.4' F	(b) (4)	28 Oct 2020 17:58:22
	Karol Moore (b) (4)	
	(b) (4)	

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Form: Symptom Log (5)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

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Form: Symptom Log (5)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

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Form: Symptom Log (5)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22



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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 17:58:22

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

**US3312023**

**Folder: Covid-19 Assessment 06 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User entered '%'	System	28 Oct 2020 18:00:38



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97.8' F	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38



US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:00:38

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:00:38
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:00:38

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '96'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User entered '%'	System	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.2' F	(b) (4)	28 Oct 2020 18:02:40
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40



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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4)	28 Oct 2020 18:02:40
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40



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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:02:40

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Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:02:40

**US3312023**

**Folder: Covid-19 Assessment 06 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16



US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

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 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[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 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16

**US3312023**

**Folder: Covid-19 Assessment 06 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4)	28 Oct 2020 18:03:16

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[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 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:03:16



US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:31
User entered '0'	System	28 Oct 2020 18:03:16

US3312023

Folder: Covid-19 Assessment 06 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:01:52

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	10 Dec 2020 22:04:56

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:38:00

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:01:52**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12:03'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:38:00

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:01:52**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:38
User entered '12 Feb 2021 12:03'	System	18 Feb 2021 16:38:00

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:52

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Safety Call (Safety Call)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:38:00

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:52

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:38:00

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52



**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '05 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:52:52

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:52:52

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '06 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:27

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '07 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:53:51



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:51

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:53:51



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:53:51

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 4 (Day 4)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '08 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:18



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:18

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:18

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43



**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '09 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:43



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:54:43

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:54:43

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '10 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20



**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:58:20

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:58:20



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:58:20

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '11 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:59:07



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Folder: Covid-19 Assessment 12 Feb 2021

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:07

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4)	18 Feb 2021 16:59:07
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:07

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:07

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:07

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 8 (Day 8)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:42



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:42

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**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:59:42

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:59:42

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 9 (Day 9)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '13 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

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**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:00:03

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 17:00:03

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:00:03

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:00:03

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 10 (Day 10)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '14 Feb 2021'	(b) (4)	18 Feb 2021 17:01:33
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 17:01:33

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:01:33

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:01:33

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 11 (Day 11)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '15 Feb 2021'	(b) (4)	18 Feb 2021 17:02:10
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 17:02:10



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Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10



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Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:02:10

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 12 (Day 12)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '16 Feb 2021'	(b) (4)	18 Feb 2021 17:03:05
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '100'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:03:05

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	18 Feb 2021 17:03:05

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.6' F	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:03:05

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05



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Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05



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Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:03:05

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 17:03:05

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 13 (Day 13)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53



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Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '17 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

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**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	22 Feb 2021 21:32:53

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97.9' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53



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Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:32:53

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:32:53

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53



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Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

US3312023

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

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Form: Symptom Log (13)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:32:53

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:32:53

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 14 (Day 14)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '18 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

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**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11



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Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	22 Feb 2021 21:33:11

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11



US3312023

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Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:11

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:11

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 15 (Day 15)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '19 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	22 Feb 2021 21:33:36



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:36

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36



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Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:36

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 16 (Day 16)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '20 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 17:01:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	22 Feb 2021 21:33:58

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:58



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Folder: Covid-19 Assessment 12 Feb 2021

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Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58



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Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:58

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:33:58

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:33:58

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Form: Symptom Log (17)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Day 17 (Day 17)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19



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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '21 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User entered '%'	System	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19



US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	22 Feb 2021 21:34:19

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:01:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:19

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '16 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35

**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:01:52**

[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 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[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 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35



**US3312023**

**Folder: Covid-19 Assessment 12 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '16 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4)	22 Feb 2021 21:34:35

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[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 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:34:35

US3312023

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:52

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:07:46
User entered '0'	System	22 Feb 2021 21:34:35

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:28:51



**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered '08 Oct 2020'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:28:51

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

US3312023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:01:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:28:51

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	



**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:28:51

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:28:51

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:28:51

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	



**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:28:51

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

**US3312023**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	28 Oct 2020 18:28:51
	(b) (4)	

US3312023

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:01:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:38:47

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	18 Feb 2021 16:38:47
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered '18 Feb 2021' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Feb 2021 16:38:57
	(b) (4)	
User entered '16 Feb 2021'	Karol Moore (b) (4)	18 Feb 2021 16:38:47
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:35:16



**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered '20 Feb 2021'	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:35:16

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

US3312023

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:01:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:35:16

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	



**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:35:16

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:35:16

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	22 Feb 2021 21:35:16

**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	



**US3312023**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:35:16
	(b) (4)	

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:36:12
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:40:58

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:36:12
User entered '06 Oct 2020'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:40:58

US3312023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:36:12
User entered 'Clinic (Clinic)'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:40:58

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'SICKD1'	System	30 Oct 2020 18:40:58

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '06 Oct 2020'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '10:25'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39



**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered '06 Oct 2020 10:25'	System	30 Oct 2020 18:41:39

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '68' in	Karol Moore (b) (4)	30 Oct 2020 18:41:39
DataPoint set to visible.	(b) (4) System	30 Oct 2020 18:40:58

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '184' lb	Karol Moore (b) (4)	30 Oct 2020 18:41:39
DataPoint set to visible.	(b) (4) System	30 Oct 2020 18:40:58

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '98.4' F	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered empty.	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '69'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'bpm'	System	30 Oct 2020 18:41:39



US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '14'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:39

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'breaths/min'	System	30 Oct 2020 18:41:39

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Un-verified.	(b) (4)	
	Monica Atwood (b) (4)	02 Feb 2021 19:49:31
User entered '145' reason for change: Data Entry Error	(b) (4)	
	Monica Atwood (b) (4)	02 Feb 2021 19:49:31
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '146'	Karol Moore (b) (4)	30 Oct 2020 18:41:39
	(b) (4)	

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'mmHg'	System	30 Oct 2020 18:41:39

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Un-verified.	(b) (4)	
	Monica Atwood (b) (4)	02 Feb 2021 19:49:31
User entered '81' reason for change: Data Entry Error	(b) (4)	
	Monica Atwood (b) (4)	02 Feb 2021 19:49:31
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 17:37:03
User entered '76'	Karol Moore (b) (4)	30 Oct 2020 18:41:39
	(b) (4)	

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'mmHg'	System	30 Oct 2020 18:41:39

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32



US3312023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:46

US3312023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:37:14
User entered '06 Oct 2020'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:46

US3312023

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:01:52

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:41:01
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:55

US3312023

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:01:52

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:41:01
User entered '06 Oct 2020'	Karol Moore (b) (4) (b) (4)	30 Oct 2020 18:41:55

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:40:44

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '16 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:40:44

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:40:44

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'SICKD1'	System	18 Feb 2021 16:40:44



US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '16 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '10:09'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered '16 Feb 2021 10:09'	System	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '68' in	(b) (4)	18 Feb 2021 16:45:04
DataPoint set to visible.	Karol Moore (b) (4)	18 Feb 2021 16:40:44
	(b) (4)	
	System	

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '182.2' lb	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:45:04
DataPoint set to visible.	(b) (4) System	18 Feb 2021 16:40:44

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.6' F	(b) (4)	18 Feb 2021 16:45:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04



**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '60'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'bpm'	System	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'breaths/min'	System	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '139'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'mmHg'	System	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '82' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	18 Feb 2021 16:45:15
	(b) (4)	
User entered '80'	Karol Moore (b) (4)	18 Feb 2021 16:45:04
	(b) (4)	



US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered 'mmHg'	System	18 Feb 2021 16:45:04

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32

US3312023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32

US3312023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:22

**US3312023**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:01:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '16 Feb 2021'	(b) (4)	18 Feb 2021 16:45:22
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:01:52

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Feb 2021 16:45:43

**US3312023**

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 09 Jun 2021 17:01:52**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '16 Feb 2021'	(b) (4) Karol Moore (b) (4)	18 Feb 2021 16:45:43

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 18:45:53
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:45:53
	(b) (4)	
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 18:45:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:45:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:08
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	28 Oct 2020 18:09:01
	(b) (4)	



US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:08
	(b) (4)	
User entered '06 Oct 2020'	Karol Moore (b) (4)	28 Oct 2020 18:09:01
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 18:45:53
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 18:45:32
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Karol Moore (b) (4)	28 Oct 2020 18:09:01
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	28 Oct 2020 18:09:01

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	30 Oct 2020 18:45:45
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	30 Oct 2020 18:42:56
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered '06 Oct 2020'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered '10:25'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:42:56
User entered '06 Oct 2020 10:25'	System	28 Oct 2020 18:27:46

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered '98.4' F	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	



US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered 'Oral (Oral)'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered '69'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:42:56
User entered 'bpm'	System	28 Oct 2020 18:27:46

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered '14'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:42:56
User entered 'breaths/min'	System	28 Oct 2020 18:27:46

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered '146'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:42:56
User entered 'mmHg'	System	28 Oct 2020 18:27:46



US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:56
	(b) (4)	
User entered '76'	Karol Moore (b) (4)	28 Oct 2020 18:27:46
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:42:56
User entered 'mmHg'	System	28 Oct 2020 18:27:46

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:20
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	28 Oct 2020 18:27:56
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:20
	(b) (4)	
User entered '06 Oct 2020'	Karol Moore (b) (4)	28 Oct 2020 18:27:56
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:01:52

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:29
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	28 Oct 2020 18:28:10
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:01:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	30 Oct 2020 18:42:29
	(b) (4)	
User entered '06 Oct 2020'	Karol Moore (b) (4)	28 Oct 2020 18:28:10
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	22 Feb 2021 21:34:48
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:48
	(b) (4)	



US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:48
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	22 Feb 2021 21:34:48

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:34:52

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	



US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:34:52

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:34:52

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	

**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:34:52

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:52
	(b) (4)	



**US3312023**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:34:52

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	22 Feb 2021 21:34:56
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:34:56
	(b) (4)	

US3312023

**Folder: Convalescence Visit Day 28 (1)**

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

**Generated On: 09 Jun 2021 17:01:52**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	22 Feb 2021 21:35:01
	(b) (4)	

US3312023

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:01:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	22 Feb 2021 21:35:01
	(b) (4)	

US3312023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:07:10

**US3312023**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:07:10

US3312023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:07:10



**US3312023**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:01:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 15:07:10

US3312023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:07:45

**US3312023**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:01:52**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:13:36

US3312023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:07:45

**US3312023**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:01:52**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
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 12:13:36

US3312023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:07:45

US3312023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:07:45

**US3312023**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:01:52**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:56:54
User entered 'mRNA-1273 (mRNA-1273)'	Karol Moore (b) (4)	13 Jan 2021 15:07:45
	(b) (4)	



**US3312023**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:01:52**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:56:54
User entered 'mRNA-1273 (mRNA-1273)'	Karol Moore (b) (4)	13 Jan 2021 15:07:45
	(b) (4)	

**US3312023**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:01:52**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:07:45

**US3312023**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:01:52**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered empty.	System	13 Jan 2021 15:07:45

**US3312023**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:01:52**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered empty.	System	13 Jan 2021 15:07:45

US3312023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:08:00

US3312023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:08:00

**US3312023**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '09:16'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:08:00

**US3312023**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered '12 Jan 2021 09:16'	System	13 Jan 2021 15:08:00



**US3312023**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:01:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:08:11

US3312023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:08:11

US3312023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '09:15' reason for change: Data Entry Error	System	13 Jan 2021 15:08:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Karol Moore (b) (4)	13 Jan 2021 15:08:14
User entered '09:' (non-conformant).	(b) (4)	
	System	13 Jan 2021 15:08:11
	Karol Moore (b) (4)	13 Jan 2021 15:08:11
	(b) (4)	

**US3312023**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:01:52**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered '12 Jan 2021 09:15'	System	13 Jan 2021 15:08:14
User entered '12 Jan 2021 09:' (non-conformant).	System	13 Jan 2021 15:08:11

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:23:18

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:18

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:18

US3312023

Folder: **Unscheduled 12 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:01:52**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:23:18



**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 17:01:52**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '0'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:23:18

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '09:32'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User entered '12 Jan 2021 09:32'	System	13 Jan 2021 15:23:44

US3312023

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '98.6' F	(b) (4)	13 Jan 2021 15:23:44
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44



**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '60'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User entered 'bpm'	System	13 Jan 2021 15:23:44

US3312023

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User entered 'breaths/min'	System	13 Jan 2021 15:23:44

US3312023

Folder: Unscheduled 12 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '128'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User entered 'mmHg'	System	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '61'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:44

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37
User entered 'mmHg'	System	13 Jan 2021 15:23:44



**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:01:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:37

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:01:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:23:52

**US3312023**

**Folder: Unscheduled 12 Jan 2021**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:01:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:15:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '12 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:23:52

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:01:52**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:18:15

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:52
Data point term sent to Coder	System	18 Aug 2020 20:24:56
User entered 'left wrist fracture'	Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4)	
Query 'Per CDM: Response is required. Please provide.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:08:11
User entered 'No (N)'		
	Karol Moore (b) (4)	28 Oct 2020 18:29:41
	(b) (4)	
	Karol Moore (b) (4)	28 Oct 2020 18:29:36
	(b) (4)	
User opened query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:25:56
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:35:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:29:32
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 15:50:18
User entered '14 Aug 2020'	Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

US3312023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
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).	(b) (4)	18 Aug 2020 20:24:46
User entered empty; reason for change Data Entry Error	Kelly Moen (b) (4)	18 Aug 2020 20:24:46
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	18 Aug 2020 20:24:24
User entered '20:00'	Kelly Moen (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User entered empty.	System	18 Aug 2020 20:24:46
User entered '14 Aug 2020 20:00'	System	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 18:30:03
User entered 'Yes (Y)'	Karol Moore (b) (4)	18 Aug 2020 20:24:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
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)	28 Oct 2020 18:30:15
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Oct 2020 18:30:15
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	28 Oct 2020 18:30:03
User entered '25 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	28 Oct 2020 18:30:03
User entered empty.	(b) (4)	18 Aug 2020 20:24:24
	Kelly Moen (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User entered empty.	System	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

US3312023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

US3312023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 20:24:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 20:24:46
User entered 'None (NONE)' reason for change: Data Entry Error	Kelly Moen (b) (4)	18 Aug 2020 20:24:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 20:24:24
User entered empty.	System	18 Aug 2020 20:24:24
	Kelly Moen (b) (4)	18 Aug 2020 20:24:24
	(b) (4)	



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

US3312023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	28 Oct 2020 18:30:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Kelly Moen (b) (4)	18 Aug 2020 20:24:24
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:24:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
Amendment Manager: User entered '0'	System	21 Aug 2020 03:35:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:35:25

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
Amendment Manager: User entered '1'	System	21 Aug 2020 03:35:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:35:25



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:23
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:35:25

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Difficulty breathing - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:48:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:48:19
Data point term sent to Coder	System	28 Oct 2020 18:33:12
User entered 'difficulty breathing'	Karol Moore (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User entered empty.	System	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:32:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User entered empty.	System	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:32:16
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:32:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

US3312023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

US3312023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

US3312023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User entered '0'	System	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29
User entered 'I'	System	28 Oct 2020 18:32:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 04:25:28
Query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'NA. PER PROTOCOL, BODY ACHES REPORTED ON SYMPTOM LOG DURING CONVALESCENT PERIOD ARE "GENERALIZED BODY ACHES" AE. NAMES MUST MATCH SYMPTOM LOG' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 16:20:28
User opened query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:09:19
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:48:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:48:22
Data point term sent to Coder	System	28 Oct 2020 18:33:13
User entered 'body aches'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User entered empty.	System	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User entered empty.	System	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:33:02
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

US3312023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User entered '0'	System	28 Oct 2020 18:33:02

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36
User entered 'I'	System	28 Oct 2020 18:33:02



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:48:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:48:49
Data point term sent to Coder	System	28 Oct 2020 18:34:14
User entered 'headache'	Karol Moore (b) (4)	28 Oct 2020 18:34:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	28 Oct 2020 19:36:59
User entered '02 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	28 Oct 2020 18:34:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User entered empty.	System	28 Oct 2020 18:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '19 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User entered empty.	System	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

US3312023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

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Folder: Adverse Events

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

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Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01



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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

US3312023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User entered '0'	System	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42
User entered 'I'	System	28 Oct 2020 18:34:01

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:42

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Loss of smell - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:02
Data point term sent to Coder	System	28 Oct 2020 18:36:21
User entered 'new loss of smell'	Karol Moore (b) (4)	28 Oct 2020 18:35:43
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User entered empty.	System	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User entered empty.	System	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:35:43
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

US3312023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User entered '0'	System	28 Oct 2020 18:35:43

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45
User entered 'I'	System	28 Oct 2020 18:35:43



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:45

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47

US3312023

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:14
Data point term sent to Coder	System	28 Oct 2020 18:37:23
User entered 'nasal congestion'	Karol Moore (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

US3312023

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:36:42
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User entered empty.	System	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

US3312023

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
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)	28 Oct 2020 18:38:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Oct 2020 18:38:52
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	28 Oct 2020 18:36:42
User entered '15 Oct 2020'	Karol Moore (b) (4)	28 Oct 2020 18:36:42
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User entered empty.	System	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	28 Oct 2020 18:36:42
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:36:42
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

US3312023

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:36:42

US3312023

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

US3312023

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:01:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	28 Oct 2020 18:38:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Karol Moore (b) (4)	28 Oct 2020 18:36:42
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User entered '0'	System	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47
User entered 'I'	System	28 Oct 2020 18:36:42

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:47

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51

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Folder: Adverse Events

Form: Adverse Events (7)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:15
Data point term sent to Coder	System	28 Oct 2020 18:38:27
User entered 'runny nose'	Karol Moore (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User entered empty.	System	28 Oct 2020 18:37:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:37:29
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User entered empty.	System	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

US3312023

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:37:29
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

US3312023

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:01:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User entered '0'	System	28 Oct 2020 18:37:29

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51
User entered 'I'	System	28 Oct 2020 18:37:29



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:51

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:32
Data point term sent to Coder	System	28 Oct 2020 18:39:29
User entered 'sore throat'	Karol Moore (b) (4)	28 Oct 2020 18:38:36

US3312023

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:38:36

US3312023

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User entered empty.	System	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:38:36
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User entered empty.	System	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

US3312023

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:38:36
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

US3312023

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

US3312023

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:38:36

US3312023

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36



US3312023

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:01:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User entered '0'	System	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56
User entered 'I'	System	28 Oct 2020 18:38:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:56

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02

US3312023

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:41
Data point term sent to Coder	System	28 Oct 2020 18:40:31
User entered 'shortness of breath'	Karol Moore (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

US3312023

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User entered empty.	System	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:00
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User entered empty.	System	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

US3312023

Folder: Adverse Events

Form: Adverse Events (9)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:40:00
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:00

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:00



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:00

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:00

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Folder: Adverse Events

Form: Adverse Events (9)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

US3312023

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00



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**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

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Form: Adverse Events (9)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:00

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User entered '0'	System	28 Oct 2020 18:40:00

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02
User entered 'I'	System	28 Oct 2020 18:40:00



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:02

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:49:50
Data point term sent to Coder	System	28 Oct 2020 18:41:45
User entered 'cough'	Karol Moore (b) (4)	28 Oct 2020 18:40:39

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User entered empty.	System	28 Oct 2020 18:40:39

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:39

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '19 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User entered empty.	System	28 Oct 2020 18:40:39

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:40:39
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39



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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:39

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

US3312023

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

US3312023

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:01:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39



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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

**US3312023**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User entered '0'	System	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04
User entered 'I'	System	28 Oct 2020 18:40:39

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:04

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:54:35
Data point term sent to Coder	(b) (4)	
User entered 'fatigue'	(b) (4)	
	Coder Import (b) (4)	29 Oct 2020 19:54:35
	(b) (4)	
	System	28 Oct 2020 18:50:16
	Karol Moore (b) (4)	28 Oct 2020 18:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

US3312023

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:49:57
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User entered empty.	System	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User entered empty.	System	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:49:57
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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Folder: Adverse Events

Form: Adverse Events (11)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

US3312023

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:01:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4)	28 Oct 2020 18:49:57
	Karol Moore (b) (4)	
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User entered '0'	System	28 Oct 2020 18:49:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19
User entered 'I'	System	28 Oct 2020 18:49:57



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:19

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 04:25:50
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'NA. PER PROTOCOL, MUSCLE ACHES REPORTED ON SYMPTOM LOG DURING CONVALESCENT PERIOD ARE "GENERALIZED MUSCLE ACHES" AE. NAMES MUST MATCH SYMPTOM LOG' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 16:37:19
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:09:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:04:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:04:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:58:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:58:23
Data point term sent to Coder	System	28 Oct 2020 19:30:48

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'muscle aches'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User entered empty.	System	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User entered empty.	System	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 19:30:36
	Karol Moore (b) (4)	
	(b) (4)	



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

US3312023

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

US3312023

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36

US3312023

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

US3312023

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4)	28 Oct 2020 19:30:36
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36



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**Folder: Adverse Events**

**Form: Adverse Events (12)**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User entered '0'	System	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24
User entered 'I'	System	28 Oct 2020 19:30:36

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:24

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 04:26:11
Query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'NA. PER PROTOCOL, BODY ACHES REPORTED ON SYMPTOM LOG DURING CONVALESCENT PERIOD ARE "GENERALIZED BODY ACHES" AE. NAMES MUST MATCH SYMPTOM LOG' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 16:36:58
User opened query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:09:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:58:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:58:33
Data point term sent to Coder	System	28 Oct 2020 19:32:50
User entered 'body aches'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05



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**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 19:32:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 19:32:14
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	28 Oct 2020 19:32:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 19:32:05
User entered empty.	System	28 Oct 2020 19:32:05
	Karol Moore (b) (4)	28 Oct 2020 19:32:05
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User entered empty.	System	28 Oct 2020 19:32:05

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User entered empty.	System	28 Oct 2020 19:32:05

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05

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Generated On: 09 Jun 2021 17:01:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 19:32:05
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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Generated On: 09 Jun 2021 17:01:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05



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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05

**US3312023**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05
	(b) (4)	

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**Form: Adverse Events (13)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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Folder: Adverse Events

Form: Adverse Events (13)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

US3312023

Folder: Adverse Events

Form: Adverse Events (13)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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Folder: Adverse Events

Form: Adverse Events (13)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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Folder: Adverse Events

Form: Adverse Events (13)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05



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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:05

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:05
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User entered '0'	System	28 Oct 2020 19:32:05



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29
User entered 'I'	System	28 Oct 2020 19:32:05

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:29

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34

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Folder: Adverse Events

Form: Adverse Events (14)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:42
Data point term sent to Coder	System	28 Oct 2020 19:33:50
User entered 'headache'	Karol Moore (b) (4)	28 Oct 2020 19:32:50
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50



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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User entered empty.	System	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User entered empty.	System	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:50

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

US3312023

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:01:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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Form: Adverse Events (14)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:50

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50



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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

US3312023

Folder: Adverse Events

Form: Adverse Events (14)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:32:50
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50



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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User entered '0'	System	28 Oct 2020 19:32:50

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34
User entered 'I'	System	28 Oct 2020 19:32:50

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**Folder: Adverse Events**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:34

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51

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Form: Adverse Events (15)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:41
Data point term sent to Coder	System	28 Oct 2020 19:33:50
User entered 'nasal congestion'	Karol Moore (b) (4)	28 Oct 2020 19:33:38



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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User entered empty.	System	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

US3312023

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User entered empty.	System	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 19:33:38
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

US3312023

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38



US3312023

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

US3312023

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

US3312023

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:01:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

US3312023

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User entered '0'	System	28 Oct 2020 19:33:38



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51
User entered 'I'	System	28 Oct 2020 19:33:38

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:51

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57

US3312023

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:44
Data point term sent to Coder	System	28 Oct 2020 19:34:52
User entered 'runny nose'	Karol Moore (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User entered empty.	System	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 19:34:31
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '06 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User entered empty.	System	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 19:34:31
	Karol Moore (b) (4)	
	(b) (4)	



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

US3312023

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 17:01:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

US3312023

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:34:31

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 17:01:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

US3312023

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

US3312023

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 17:01:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 17:01:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:34:31



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

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**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User entered '0'	System	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57
User entered 'I'	System	28 Oct 2020 19:34:31

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:30:57

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03

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Folder: Adverse Events

Form: Adverse Events (17)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:58:47
Data point term sent to Coder	System	28 Oct 2020 19:35:53
User entered 'sinusitis'	Karol Moore (b) (4)	28 Oct 2020 19:35:24



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User entered empty.	System	28 Oct 2020 19:35:24

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**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

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**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '17 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

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**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User entered empty.	System	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	28 Oct 2020 19:35:24
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 19:35:24
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

US3312023

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 17:01:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:35:24

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:35:24



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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 17:01:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

US3312023

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 17:01:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

US3312023

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 17:01:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

US3312023

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 17:01:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

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**Folder: Adverse Events**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Oct 2020 19:35:24

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User entered '0'	System	28 Oct 2020 19:35:24



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**Folder: Adverse Events**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03
User entered 'I'	System	28 Oct 2020 19:35:24

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:43:24
User entered 'USA-US300-2020-mRNA-1273-P301000027'	System	29 Dec 2020 15:48:12
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 15:48:12

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Cardiomyopathies, PT: Stress cardiomyopathy, LLT: Takotsubo syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 20:14:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 20:14:35
	(b) (4)	
Data point term sent to Coder	System	28 Dec 2020 20:12:59
User entered 'Takotsubo cardiomyopathy'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'Yes (Y)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'No (N)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'No (N)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '18 Dec 2020'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	



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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Dec 2020 20:15:03
User entered empty; reason for change Data Entry Error	Heather Barker (b) (4)	28 Dec 2020 20:15:03
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	28 Dec 2020 20:12:16
User entered '10:00'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 20:15:03
User entered '18 Dec 2020 10:00'	System	28 Dec 2020 20:12:16

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:40:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 01:43:43
User entered 'No (N)'	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:12:16

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '25 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:40:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 01:43:43
User entered '19 Dec 2020'	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:12:16

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:43:14
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).	(b) (4), (b) (6)	05 Mar 2021 16:40:44
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)	20 Jan 2021 15:34:49
User entered empty.	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:12:16

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 20:12:16

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 20:15:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 20:15:03
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Heather Barker (b) (4)	28 Dec 2020 20:15:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 20:12:16
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'Yes (Y)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	



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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'I'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '18 Dec 2020'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '19 Dec 2020'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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**Form: Adverse Events (18)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'No (N)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	



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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered 'I'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:12:16
	(b) (4)	



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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:43:20
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:40:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:40:36
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:34:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 01:43:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:12:16

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:12:16

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = ECHO on 03/05/21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:26:49
User closed query 'Per DM CLR: Narrative = IMAGING. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		12 Apr 2021 06:26:47
User closed query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		12 Apr 2021 06:26:45
Query 'Per DM CLR: Narrative = ECHO on 03/05/21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not applicable- Diagnostic tests do not need to be recorded on CP per CRA' (Site from DM).		09 Apr 2021 14:36:49
Query 'Per DM CLR: Narrative = IMAGING. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not applicable- Diagnostic tests do not need to be recorded on CP per CRA' (Site from DM).		09 Apr 2021 14:36:46
Query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'not applicable - this is a diagnostic blood test' (Site from DM).		09 Apr 2021 14:36:15
User opened query 'Per DM CLR: Narrative = ECHO on 03/05/21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		24 Mar 2021 02:43:48
User opened query 'Per DM CLR: Narrative = IMAGING. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		24 Mar 2021 02:43:43

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) [REDACTED]  Carlos Fierro (b) (4) [REDACTED]	24 Mar 2021 02:43:37   12 Mar 2021 15:42:08

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SAE REPORT  SUBJECT US3312023 SITE 331 PI CARLOS FIERRO M.D. SOURCE IS PHONE CALL WITH SUBJECT, NO MED RECORDS AT THIS TIME TO CONFIRM   66 Y/O HYPERTENSIVE, HYPERLIPIDEMIC WHO DURING EMOTIONAL DURESS AT 10AM ON 18DEC20 DEVELOPED MID-STERNAL CHEST PAIN THAT RADIATED TO HER LEFT BACK ALONG WITH DIAPHORESIS, NAUSEA, FATIGUE, NO URI SYMPTOMS NOR SHORTNESS OF AIR. SHE ACTIVATED EMS, WAS EVALUATED IN ER AT APPROXIMATELY 11AM AND WAS FOUND TO HAVE BP 185/143, ELEVATED TROPONIN, CARDIAC ENLARGEMENT ON IMAGING, EF OF 25 TO 30% ON ECHOCARDIOGRAM, AND CLEAR CORONARY ARTERIES ON CARDIAC CATH. A DIAGNOSIS OF TAKOTSUBO CARDIOMYOPATHY WAS MADE. TREATMENT INCLUDED SUBLINGUAL NTG, LOVENOX, FENTANYL, VERSED, DISCONTINUATION OF LISINOPRIL AND INITIATION OF METOPROLOL AND ASPIRIN. SYMPTOMS RESOLVED BY 19DEC20. EF WAS UP TO 48% PRIOR TO DISCHARGE AND BP WAS AT 126/72. COVID TEST WAS NEGATIVE ON 17DEC20 AND NEGATIVE AGAIN TODAY AS PART OF EMPLOYMENT CHECKS. SUBJECT BACK AT WORK TODAY AND REPORTS SYMPTOMATICALLY BACK TO PRE-EVENT BASELINE AND DENIES EDEMA. SAE OF TAKOTSUBO CARDIOMYOPATHY NR TO IP OR COVID. MEDICAL RECORDS PENDING.FOLLOW UP 12JAN2021 MEDICAL RECORDS REVIEWED AND CONFIRM SUBJECT'S REPORT OF HOSPITALIZATION FOR TAKOTSUBO OR ACUTE STRESS CARDIOMYOPATHY ON 18DEC20. SUBJECT DID NOT HAVE MI. INITIAL EJECTION FRACTION ESTIMATE ON	(b) (4), (b) (6)	05 Mar 2021 16:41:44

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[Narrative](#)

Audit	User	Time (GMT)
CARDIAC CATH WAS IN 30 TO 35 PERCENT RANGE ON 18DEC2020, AND LATER ESTIMATED AT 48% ON ECHOCARDIOGRAM 19DEC2020. CARDIAC CATH SHOWED NO OCCLUSION OF CORONARY ARTERIES. SUBJECT WAS PUT ON METOPROLOL AND ASA AS PREVENTIVE MEASURES AS A RESULT OF THIS EVENT, AND SHE REPORTS THAT AT FOLLOW-UP 05JAN2021 LISINAPRIL 5MG QD WAS PRESCRIBED BY PCP. A FOLLOW-UP WITH CARDIOLOGY IS SCHEDULED FOR 12FEB21. SUBJECT IS WELL AT A VISIT AT SITE TODAY SAE OF TAKOTSUBO CARDIOMYOPATHY, G3, NR TO IP, WILL CLOSE AFTER CARd F/u.03/05/21:Card F/u done, echo normal. AE closed per PI' reason for change: Data Entry Error		
User closed query 'Per DM CLR: Narrative indicates that symptoms has already resolved. However, this AE is still ongoing. Please verify if an End date should be recorded for this AE and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:42:11
User closed query 'Per DM CLR: Narrative indicates that the subject was treated with SUBLINGUAL NTG, LOVENOX, FENTANYL and VERSED. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:42:05
Query 'Per DM CLR: Narrative indicates that the subject was treated with SUBLINGUAL NTG, LOVENOX, FENTANYL and VERSED. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 20:16:54

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that symptoms has already resolved. However, this AE is still ongoing. Please verify if an End date should be recorded for this AE and update accordingly. Otherwise, clarify.' answered with 'narrative states will close after follow up with cardiologist' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 19:29:45
User opened query 'Per DM CLR: Narrative indicates that symptoms has already resolved. However, this AE is still ongoing. Please verify if an End date should be recorded for this AE and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:06:18
User opened query 'Per DM CLR: Narrative indicates that the subject was treated with SUBLINGUAL NTG, LOVENOX, FENTANYL and VERSED. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:05:41

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SAE REPORT  SUBJECT US3312023 SITE 331 PI CARLOS FIERRO M.D. SOURCE IS PHONE CALL WITH SUBJECT, NO MED RECORDS AT THIS TIME TO CONFIRM   66 Y/O HYPERTENSIVE, HYPERLIPIDEMIC WHO DURING EMOTIONAL DURESS AT 10AM ON 18DEC20 DEVELOPED MID-STERNAL CHEST PAIN THAT RADIATED TO HER LEFT BACK ALONG WITH DIAPHORESIS, NAUSEA, FATIGUE, NO URI SYMPTOMS NOR SHORTNESS OF AIR. SHE ACTIVATED EMS, WAS EVALUATED IN ER AT APPROXIMATELY 11AM AND WAS FOUND TO HAVE BP 185/143, ELEVATED TROPONIN, CARDIAC ENLARGEMENT ON IMAGING, EF OF 25 TO 30% ON ECHOCARDIOGRAM, AND CLEAR CORONARY ARTERIES ON CARDIAC CATH. A DIAGNOSIS OF TAKOTSUBO CARDIOMYOPATHY WAS MADE. TREATMENT INCLUDED SUBLINGUAL NTG, LOVENOX, FENTANYL, VERSED, DISCONTINUATION OF LISINAPRIL AND INITIATION OF METOPROLOL AND ASPIRIN. SYMPTOMS RESOLVED BY 19DEC20. EF WAS UP TO 48% PRIOR TO DISCHARGE AND BP WAS AT 126/72. COVID TEST WAS NEGATIVE ON 17DEC20 AND NEGATIVE AGAIN TODAY AS PART OF EMPLOYMENT CHECKS. SUBJECT BACK AT WORK TODAY AND REPORTS SYMPTOMATICALLY BACK TO PRE-EVENT BASELINE AND DENIES EDEMA. SAE OF TAKOTSUBO CARDIOMYOPATHY NR TO IP OR COVID. MEDICAL RECORDS PENDING.Follow up 12Jan2021 Medical records reviewed and confirm subject's report of hospitalization for Takotsubo or acute stress cardiomyopathy on 18Dec20. Subject did not have MI. Initial ejection fraction estimate on cardiac cath was in 30 to 35 percent range on 18Dec2020, and later estimated at 48% on	(b) (4), (b) (6)	13 Jan 2021 01:43:08

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EAB) (1725)

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US3312023

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 17:01:52

[Narrative](#)

Audit	User	Time (GMT)
echocardiogram 19Dec2020. Cardiac cath showed no occlusion of coronary arteries. Subject was put on metoprolol and asa as preventive measures as a result of this event, and she reports that at follow-up 05Jan2021 lisinopril 5mg qd was prescribed by PCP. A follow-up with cardiology is scheduled for 12Feb21. Subject is well at a visit at site today SAE of Takotsubo cardiomyopathy, G3, NR to IP, will close after cardiology visit' reason for change: Data Entry Error		
User entered 'SAE report Subject US3312023 Site 331 PI Carlos Fierro M.D. Source is phone call with subject, no med records at this time to confirm	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:12:16

66 y/o hypertensive, hyperlipidemic who during emotional duress at 10am on 18Dec20 developed mid-sternal chest pain that radiated to her left back along with diaphoresis, nausea, fatigue, no URI symptoms nor shortness of air. She activated EMS, was evaluated in ER at approximately 11am and was found to have BP 185/143, elevated troponin, cardiac enlargement on imaging, EF of 25 to 30% on echocardiogram, and clear coronary arteries on cardiac cath. A diagnosis of Takotsubo cardiomyopathy was made. Treatment included sublingual NTG, lovenox, fentanyl, versed, discontinuation of lisinopril and initiation of metoprolol and aspirin. Symptoms resolved by 19Dec20. EF was up to 48% prior to discharge and BP was at 126/72. Covid test was negative on 17Dec20 and negative again today as part of employment checks. Subject back at work today and reports symptomatically back to pre-event baseline and denies edema. SAE of Takotsubo cardiomyopathy NR to IP or Covid. Medical records pending.'

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 20:12:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Dec 2020 20:12:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 20:12:16

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11

US3312023

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:01:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 15:00:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 15:00:51
Data point term sent to Coder	System	01 Mar 2021 14:45:13
User entered 'SINUSITIS'	Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '05 Feb 2021'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User entered empty.	System	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '18 Feb 2021'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User entered empty.	System	01 Mar 2021 14:45:03



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

US3312023

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:01:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03



**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03



US3312023

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 17:01:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'I'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered '0'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:42:08
User entered empty.	(b) (4) Monica Atwood (b) (4)	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User entered '0'	System	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11
User entered 'I'	System	01 Mar 2021 14:45:03

**US3312023**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:31:11



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:01:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:22:14

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 14:24:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:24:45
Data point term sent to Coder	System	13 Aug 2020 14:23:26
User entered 'Lipitor'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:22:49

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Hyperlipidemia'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '20'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	



US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 19:03:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:22:49
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:22:49

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	13 Aug 2020 14:22:49
	(b) (4)	



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:22:49

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:22:49

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:22:49

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 14:24:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 14:24:24
Data point term sent to Coder	System	13 Aug 2020 14:23:27
User entered 'celexa'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'anxiety'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '40'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	



US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 19:03:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:23:22
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:23:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	13 Aug 2020 14:23:22
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:23:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:23:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:23:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 14:25:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:25:26
Data point term sent to Coder User entered 'lisinopril'	System Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:33 13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'hypertension'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '5'	Karol Moore (b) (4)	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 19:03:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:24:11
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)' reason for change: New Information	(b) (4) Heather Barker (b) (4)	28 Dec 2020 20:23:35
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020' reason for change: New Information	(b) (4)	28 Dec 2020 20:23:35
User entered empty.	Heather Barker (b) (4)	13 Aug 2020 14:24:11
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:11

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User entered '1'	System	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User entered '1'	System	13 Aug 2020 14:24:11

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:48
User entered '804 (804)'	System	13 Aug 2020 14:24:11

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Aug 2020 14:26:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Aug 2020 14:26:29
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 14:25:34
User entered 'Tramadol'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'lower back pain'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '50'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 19:03:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:24:54
User entered '02 May 2020'	Karol Moore (b) (4) (b) (4)	13 Aug 2020 14:24:54

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	13 Aug 2020 14:24:54
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:24:54

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:24:54



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:24:54

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE BITARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:17:55
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:17:55
User closed query 'Per DM CLR: Please review if this is a combination or single product as the dose recorded is for a combination drug. If so, please update the medication name to list the brand or each component otherwise update dose field. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:16:50
Query 'Per DM CLR: Please review if this is a combination or single product as the dose recorded is for a combination drug. If so, please update the medication name to list the brand or each component otherwise update dose field. Please update as appropriate.' answered with 'updated' (Site from DM).	Karol Moore (b) (4)	28 Oct 2020 16:41:26
Data point term sent to Coder	System	28 Oct 2020 16:40:07
Coding entries removed.	Karol Moore (b) (4)	28 Oct 2020 16:39:13
User entered 'HYDROCODONE (bitartrate/acetaminophen)' reason for change: Data Entry Error	Karol Moore (b) (4)	28 Oct 2020 16:39:13
User opened query 'Per DM CLR: Please review if this is a combination or single product as the dose recorded is for a combination drug. If so, please update the medication name to list the brand or each component otherwise update dose field. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:01:51

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:50:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:50:23
Data point term sent to Coder	System	18 Aug 2020 20:30:16
User entered 'Hydrocodone'	Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 08:16:57
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'this is listed as AE #1' (Site from DM).	Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:41:18
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:02:06
User entered 'left wrist fracture'	Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '5/325'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'as needed (PRN)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '15 Aug 2020'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Sep 2020 20:46:13
User entered 'Yes (Y)'	Monica Atwood (b) (4)	18 Aug 2020 20:30:05
	(b) (4)	
	Kelly Moen (b) (4)	
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	20 Sep 2020 20:46:13
User entered empty.	Monica Atwood (b) (4)	18 Aug 2020 20:30:05
	(b) (4)	



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User entered empty.	System	18 Aug 2020 20:30:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User entered empty.	System	18 Aug 2020 20:30:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:52
User entered empty.	System	18 Aug 2020 20:30:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
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)	26 Aug 2020 14:54:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:54:42
Data point term sent to Coder	System	26 Aug 2020 14:48:06
User entered 'naproxen'	Karol Moore (b) (4)	26 Aug 2020 14:47:34

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 08:17:27
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'condition is listed as AE#1' (Site from DM).	Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:41:58
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:02:40
User entered 'left wrist fracture'	Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '440'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'as needed (PRN)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	26 Aug 2020 14:47:34

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:02:24
User entered 'Yes (Y)'	Karol Moore (b) (4)	26 Aug 2020 14:47:34
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:02:24
User entered empty.	Karol Moore (b) (4)	26 Aug 2020 14:47:34
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User entered empty.	System	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User entered empty.	System	26 Aug 2020 14:47:34

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:55
User entered empty.	System	26 Aug 2020 14:47:34

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:52:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:52:20
Data point term sent to Coder User entered 'levaquin'	System Karol Moore (b) (4)	28 Oct 2020 16:47:30 28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'sinusitis'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '500'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4)	28 Oct 2020 16:47:26
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '08 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '17 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:47:26

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4)	28 Oct 2020 16:47:26
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User entered '1'	System	28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User entered '1'	System	28 Oct 2020 16:47:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:59
User entered '804 (804)'	System	28 Oct 2020 16:47:26



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:37:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:37:33
Data point term sent to Coder	System	28 Oct 2020 16:52:39
User entered 'ibuprofen'	Karol Moore (b) (4)	28 Oct 2020 16:52:20

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'sinusitis/headache'	Karol Moore (b) (4)	28 Oct 2020 16:52:20

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '200'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'three times daily (TID)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (08OCT2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 08:47:41
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (08OCT2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'correct as entered. see ae line #14' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:10:00
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (08OCT2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 09:13:45
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '12 Oct 2020'	(b) (4) Karol Moore (b) (4)	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 16:52:20

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User entered '3'	System	28 Oct 2020 16:52:20



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User entered '1'	System	28 Oct 2020 16:52:20

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:05
User entered '804 (804)'	System	28 Oct 2020 16:52:20

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
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)	03 Nov 2020 21:03:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:03:32
Data point term sent to Coder	System	03 Nov 2020 21:03:20
User entered 'seasonal influenza vaccine'	Karol Moore (b) (4)	03 Nov 2020 21:03:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'seasonal influenza prophylaxis'	Karol Moore (b) (4)	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0.5' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:21:36
User entered '1'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:21:36
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:21:36
User entered 'injection'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once (ONCE)'	(b) (4)	03 Nov 2020 21:03:17
	Karol Moore (b) (4)	
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Karol Moore (b) (4)	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '27 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Nov 2020 21:03:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User entered empty.	System	03 Nov 2020 21:03:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User entered empty.	System	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:08
User entered empty.	System	03 Nov 2020 21:03:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Dec 2020 20:34:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 20:34:29
Data point term sent to Coder	System	28 Dec 2020 20:33:18
User entered 'ASA'	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:32:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Cardiac prophylaxis'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '81'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'mg (mg)'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'once daily (QD)'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '18 Dec 2020'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Heather Barker (b) (4)	28 Dec 2020 20:32:26
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 20:32:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 20:32:26

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Dec 2020 20:32:26

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:43:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 19:35:34
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 Feb 2021 19:35:34
Data point term sent to Coder	System	09 Feb 2021 19:34:32
Data point term sent to Coder	System	09 Feb 2021 19:33:32
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'taken for takotsubo cardiomyopathy and hypertenison' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 19:33:11
Coding entries removed.	(b) (4), (b) (6)	09 Feb 2021 19:32:54
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:16:33

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 20:43:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 20:43:23
Data point term sent to Coder Coding entries removed.	System Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:42:31 28 Dec 2020 20:41:45
User entered 'METOPROLOL' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:41:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 20:35:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 20:35:28
Data point term sent to Coder User entered 'metoprolo'	System Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:34:19 28 Dec 2020 20:33:21



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'HYPERTENSION' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:18
User entered 'takotsubo cardiomyopathy and HYPERTENSION' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 19:32:54
User entered 'hypertension'	Heather Barker (b) (4) (b) (4)	28 Dec 2020 20:33:21

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User closed query 'Per CDM: Please complete this mandatory field. Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:48:39
Query 'Per CDM: Please complete this mandatory field. Thank you!' answered with 'updated per source' (Site from DM).	Karol Moore (b) (4)	13 Jan 2021 15:10:36
	(b) (4)	
User entered '25' reason for change: Data Entry Error	Karol Moore (b) (4)	13 Jan 2021 15:10:27
	(b) (4)	
User opened query 'Per CDM: Please complete this mandatory field. Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 10:08:30
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	06 Jan 2021 10:08:17
Query 'Per CDM: Please complete this mandatory field. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 10:08:16
User opened query 'Per CDM: Please complete this mandatory field. Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 10:08:14
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 20:33:21
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'mg (mg)'	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User closed query 'Per CDM: Please complete this mandatory field. Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:48:36
Query 'Per CDM: Please complete this mandatory field. Thank you!' answered with 'updated per source' (Site from DM).	Karol Moore (b) (4)	13 Jan 2021 15:10:40
	(b) (4)	
User entered 'once daily (QD)' reason for change: Data Entry Error	Karol Moore (b) (4)	13 Jan 2021 15:10:27
	(b) (4)	
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	06 Jan 2021 10:08:38
User opened query 'Per CDM: Please complete this mandatory field. Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 10:08:35
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 20:33:21
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	



US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '18 Dec 2020'	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '0'	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	Heather Barker (b) (4)	28 Dec 2020 20:33:21
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:10:27
User entered empty.	System	28 Dec 2020 20:33:21

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:10:27
User entered empty.	System	28 Dec 2020 20:33:21



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:10:27
User entered empty.	System	28 Dec 2020 20:33:21

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Jan 2021 15:12:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:12:01
Data point term sent to Coder User entered 'lisinopril'	System Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:28 13 Jan 2021 15:11:13

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:13

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'hypertension'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:13

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '5'	Karol Moore (b) (4)	13 Jan 2021 15:11:13

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:13

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:11:13

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once daily (QD)'	Karol Moore (b) (4)	13 Jan 2021 15:11:13



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4)	13 Jan 2021 15:11:13
	Karol Moore (b) (4)	
	(b) (4)	

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:13

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) Karol Moore (b) (4)	13 Jan 2021 15:11:13

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '31 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:13

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:13

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 21:36:20
User entered 'Yes (Y)'	Karol Moore (b) (4)	13 Jan 2021 15:11:13
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 21:36:20
User entered empty.	Karol Moore (b) (4)	13 Jan 2021 15:11:13
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:13



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User entered '1'	System	13 Jan 2021 15:11:13

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User entered '1'	System	13 Jan 2021 15:11:13

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:13
User entered '804 (804)'	System	13 Jan 2021 15:11:13

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 18:08:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:46:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:46:11
Data point term sent to Coder	System	23 Feb 2021 15:45:00
User entered 'Pantoprazole'	(b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Gastroesophageal reflux disease prophylaxis'	(b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '40'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '20 Dec 2020'	(b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:11:45

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 15:44:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Feb 2021 15:42:11
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4)	13 Jan 2021 15:11:45
	(b) (4)	

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Feb 2021 15:52:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:52:00
Data point term sent to Coder	System	23 Feb 2021 15:51:21
User entered 'Gabapentin'	(b) (4), (b) (6)	23 Feb 2021 15:51:09

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 15:51:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 15:51:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 15:51:16
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 15:51:09
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'osteoarthritis'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:51:09



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '300'	(b) (4), (b) (6)	23 Feb 2021 15:51:09

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Feb 2021 15:51:09

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:51:09

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:51:09

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Feb 2021 15:51:09

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'un UNK 2017'	(b) (4), (b) (6)	23 Feb 2021 15:51:09



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:51:09

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:51:09

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 15:51:09

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	17 Mar 2021 11:49:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	17 Mar 2021 11:49:45
Data point term sent to Coders	System	01 Mar 2021 14:58:24
User entered 'NITROGLYCERIN'	(b) (4), (b) (6)	01 Mar 2021 14:58:22



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'TAKOTSUBO CARDIOMYOPATHY'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0.3'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'SUBLINGUAL'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User entered empty.	System	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User entered empty.	System	01 Mar 2021 14:58:22



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:20
User entered empty.	System	01 Mar 2021 14:58:22

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 22:37:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 22:37:54
Data point term sent to Coder	System	01 Mar 2021 14:59:24
User entered 'LOVENOX'	(b) (4), (b) (6)	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'TAKOTSUBO CARDIOMYOPATHY'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '40'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:01:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:59:17



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User entered empty.	System	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User entered empty.	System	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:24
User entered empty.	System	01 Mar 2021 14:59:17

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 07:44:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 07:44:22
Data point term sent to Coder	System	01 Mar 2021 15:01:28
User entered 'FENTANYL'	(b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'TAKOTSUBO CARDIOMYOPATHY'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '50'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User entered empty.	System	01 Mar 2021 15:00:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User entered empty.	System	01 Mar 2021 15:00:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:31
User entered empty.	System	01 Mar 2021 15:00:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:29:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:29:04
Data point term sent to Coder	System	01 Mar 2021 15:02:28
User entered 'VERSED'	(b) (4), (b) (6)	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'TAKOTSUBO CARDIOMYOPATHY'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '2'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User entered empty.	System	01 Mar 2021 15:01:52

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User entered empty.	System	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:35
User entered empty.	System	01 Mar 2021 15:01:52

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
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, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:59:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:59:40
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:08:36
Data point term sent to Coder	System	07 Apr 2021 15:16:17
Coding entries removed.	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 15:15:58
User entered 'AUGMENTIN (AMOXICILLIN/CLAVULANIC ACID)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 15:15:58
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, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 15:03:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 15:03:51
Data point term sent to Coder	System	01 Mar 2021 15:03:29
User entered 'AUGMENTIN'	(b) (4), (b) (6) (b) (4)	01 Mar 2021 15:03:18



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'SINUSITIS'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:11:13
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' ' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4)	07 Apr 2021 15:16:20
	(b) (4)	
User entered '875/125' reason for change: Data Entry Error	Monica Atwood (b) (4)	07 Apr 2021 15:15:58
	(b) (4)	
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:34:30
User entered '875' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 17:43:31
User entered '1750'	(b) (4), (b) (6)	01 Mar 2021 15:03:18

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:03:18

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User entered '2'	System	01 Mar 2021 15:03:18

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User entered '1'	System	01 Mar 2021 15:03:18



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:39
User entered '804 (804)'	System	01 Mar 2021 15:03:18

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 15:05:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 15:05:50
Data point term sent to Coder	System	01 Mar 2021 15:04:41
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'SINUSITIS'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '1000'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:05



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User entered empty.	System	01 Mar 2021 15:04:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User entered empty.	System	01 Mar 2021 15:04:05

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:43:43
User entered empty.	System	01 Mar 2021 15:04:05

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:52

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if the dose of this med was increased because the patient's medical history of HYPERTENTION worsened. If yes, please review if an AE of worsening HYPERTENTION should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:11:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
Query 'Per DM CLR: Please review if the dose of this med was increased because the patient's medical history of HYPERTENTION worsened. If yes, please review if an AE of worsening HYPERTENTION should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'CONFIRMED NO WORSENING OR EXACERBATION, NOT AN AE' (Site from DM).	Monica Atwood (b) (4)	07 Apr 2021 15:19:58
User opened query 'Per DM CLR: Please review if the dose of this med was increased because the patient's medical history of HYPERTENTION worsened. If yes, please review if an AE of worsening HYPERTENTION should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:34:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 15:06:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 15:06:50
Data point term sent to Coder	System	01 Mar 2021 15:05:43
User entered 'LISINOPRIL'	(b) (4), (b) (6)	01 Mar 2021 15:04:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'HYPERTENTION'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
	(b) (4)	
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 17:43:47
User entered '20'	(b) (4), (b) (6)	01 Mar 2021 15:04:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48



US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

US3312023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48



**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

US3312023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:08:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 15:04:48

**US3312023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:01:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 15:04:48

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:01:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Aug 2020 20:30:50

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:01:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered '19 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	11 Sep 2020 16:21:17
	(b) (4)	
User entered '18 Aug 2020'	Kelly Moen (b) (4)	18 Aug 2020 21:09:47
	(b) (4)	

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:01:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'surgical repair left wrist fracture'	Kelly Moen (b) (4)	18 Aug 2020 21:09:47
	(b) (4)	



**US3312023**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered 'Adverse Event (AE)'	Kelly Moen (b) (4)	18 Aug 2020 21:09:47
	(b) (4)	

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:01:52

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
	(b) (4)	
User entered empty.	Kelly Moen (b) (4)	18 Aug 2020 21:09:47
	(b) (4)	

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:01:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '18 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:11

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:01:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'cardiac catheterization'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:11

**US3312023**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Adverse Event (AE)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:11

**US3312023**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 17:01:52**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:11

**US3312023**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:01:52**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '19 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:35

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:01:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'echocardiogram'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:35



**US3312023**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'Adverse Event (AE)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:35

US3312023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:01:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 15:12:35

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'USA-US300-2020-MRNA-1273-P301000027'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Carlos'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Fierro'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '16300 College Blvd'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Shawnee'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'KS'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '66219'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:06:05
User entered 'US'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 14:43:46
User entered '2'	System	13 Jan 2021 16:06:15
User entered '1'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'USA-US300-2020-MRNA-1273-P301000027'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Carlos'	System	29 Dec 2020 15:48:12

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Fierro'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '16300 College Blvd'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Shawnee'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'KS'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '66219'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:06:05
User entered 'US'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 14:43:46
User entered '2'	System	13 Jan 2021 16:06:15
User entered '1'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '29/Dec/2020 10:49'	(b) (4) System	29 Dec 2020 15:49:26

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:01:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:06:05
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'USA-US300-2020-MRNA-1273-P301000027'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Carlos'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Fierro'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '16300 College Blvd'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Shawnee'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'KS'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '66219'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:06:05
User entered 'US'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 14:43:46
User entered '2'	System	13 Jan 2021 16:06:15
User entered '1'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '13/Jan/2021 16:06'	(b) (4) System	13 Jan 2021 16:06:15

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:01:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:06:15

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'USA-US300-2020-MRNA-1273-P301000027'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Yes (Y)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'No (N)'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Carlos'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Fierro'	System	29 Dec 2020 15:48:12



**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '16300 College Blvd'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'Shawnee'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered 'KS'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:48:54
User entered '66219'	System	29 Dec 2020 15:48:12

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:06:05
User entered 'US'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:01:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 14:43:46
User entered '2'	System	13 Jan 2021 16:06:15
User entered '1'	System	29 Dec 2020 15:49:26

**US3312023**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000027**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:01:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered '08/Mar/2021 09:43'	(b) (4) System	08 Mar 2021 14:43:46

US3312023

Folder: SAE USA-US300-2020-MRNA-1273-P301000027

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:01:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:22:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:43:46