

US3312291 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3312291

Form: Participant Creation

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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Participant ID

US3312291

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

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US3312291

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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 22:32:24

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Date of Birth (MMM yyyy)	(b) (6) 1956
Age	63
Age Units	YEARS
Age (Derived)	63
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 22:32:24

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	26 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 type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:32:24

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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 22:32:24

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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 22:32:24

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Condition	GASTROESOPHAGEAL REFLUX DISEASE
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 (2)

Data signed: (b) (4) 15 Feb 2021 22:32:24

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Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Condition	BILATERAL SALPINGO-OOPHORECTOMY
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 22:32:24

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Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	26 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:05 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:05
Height ( <i>xxx.x</i> )	64 in
Weight ( <i>xxx.x</i> )	191 lb
BMI ( <i>xxx.x</i> )	32.85363 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:32:24

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 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 22:32:24

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Date of assessment (dd MMM yyyy) 26 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) UN UNK 2006

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:32:24

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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 22:32:24

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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 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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 22:32:24

Generated On: 09 Jun 2021 16:58:08

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108440

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 22:32:24

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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 22:32:24

Generated On: 09 Jun 2021 16:58:08

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)	26 AUG 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:05
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 22:32:24

Generated On: 09 Jun 2021 16:58:08

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)	26 AUG 2020
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:34
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: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 11:03 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 11:03

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	10:33 (24 HR)
Collection date and time (derived)	26 AUG 2020 10:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:26	26 AUG 2020 10:26
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

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 16:58:08

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 11:35

PC Open Date & Time

26 AUG 2020 11:23

PC Close Date & Time

26 AUG 2020 13:53

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	26 AUG 2020 23:26
PC Open Date & Time	26 AUG 2020 14:48
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**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

96.3 °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

27 AUG 2020 12:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**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

96.7 °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

28 AUG 2020 19:22

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

29 AUG 2020 12:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59



US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**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

96.6 °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

30 AUG 2020 16:25

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**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

96.7 °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

31 AUG 2020 13:41

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**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

96.6 °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

01 SEP 2020 13:17

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 11:35

PC Open Date & Time

26 AUG 2020 11:23

PC Close Date & Time

26 AUG 2020 13:53

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**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

26 AUG 2020 23:26

PC Open Date & Time

26 AUG 2020 14:48

PC Close Date & Time

27 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 19:22

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**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

29 AUG 2020 12:15

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**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

30 AUG 2020 16:26

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**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

31 AUG 2020 13:41

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**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

01 SEP 2020 13:18

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**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 ☐

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 11:36
PC Open Date & Time	26 AUG 2020 11:23
PC Close Date & Time	26 AUG 2020 13:53

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**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 ☐

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 23:27
PC Open Date & Time	26 AUG 2020 14:48
PC Close Date & Time	27 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2642

EAB) (1725)

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 19:22
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

51 of 2642

EAB) (1725)

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:15
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2642

EAB) (1725)

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 16:26
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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 ☒

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EAB) (1725)



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 13:42
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**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 ☒

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 13:18
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3312291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312291

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

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)	23 SEP 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:33
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

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)	23 SEP 2020
Time of assessment (00:00-23:59)	13:54 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:54
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3312291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 13:23 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 13:23

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

US3312291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

12:57 (24 HR)

Collection date and time (derived)

23 SEP 2020 12:57

US3312291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:54	23 SEP 2020 12:54
Nasopharyngeal Swab 2	No		



US3312291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**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

98.2 °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

23 SEP 2020 13:59

PC Open Date & Time

23 SEP 2020 13:43

PC Close Date & Time

23 SEP 2020 16:13

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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	23 SEP 2020 21:15
PC Open Date & Time	23 SEP 2020 17:08
PC Close Date & Time	24 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 09:35

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**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

97.3 °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

25 SEP 2020 13:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**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

97.3 °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

26 SEP 2020 15:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 16:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**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

96.7 °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

28 SEP 2020 15:51

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**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

97.3 °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

30 SEP 2020 05:20

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 13:59

PC Open Date & Time

23 SEP 2020 13:43

PC Close Date & Time

23 SEP 2020 16:13

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**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

23 SEP 2020 21:16

PC Open Date & Time

23 SEP 2020 17:08

PC Close Date & Time

24 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 09:35

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 13:22

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**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

26 SEP 2020 15:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**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

27 SEP 2020 16:04

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**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

28 SEP 2020 15:51

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**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

30 SEP 2020 05:20

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**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 ☐

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 14:00
PC Open Date & Time	23 SEP 2020 13:43
PC Close Date & Time	23 SEP 2020 16:13

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**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 ☐

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 21:16
PC Open Date & Time	23 SEP 2020 17:08
PC Close Date & Time	24 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 09:36
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 13:22
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 15:33
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 16:04
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 15:52
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**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 ☒



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 05:20
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3312291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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



US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	09:47 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 09:47
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

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.*

US3312291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	09:56 (24 HR)
Collection date and time (derived)	21 OCT 2020 09:56

US3312291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:32:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 09:17:43

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3312291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

05 NOV 2020 14:37:17

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3312291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

11 NOV 2020 16:54:20

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 07:26:56
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59



US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 15:56:01
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 12:27:35

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 12:00:38
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

18 DEC 2020 09:21:47

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 14:54:32

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 12:00:36
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 23:34:40

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

15 JAN 2021 08:07:28

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59



US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

24 JAN 2021 12:02:26

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

31 JAN 2021 12:00:21

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 12:00:44
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

12 FEB 2021 09:18:22

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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	19 FEB 2021 11:02:55
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 09:45:03

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 14:02:52
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 15:15:12
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59



US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

21 MAR 2021 12:30:08

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

26 MAR 2021 11:14:39

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

04 APR 2021 12:19:16

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

12 APR 2021 14:57:39

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

<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	17 APR 2021 20:35:35
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

23 APR 2021 13:59:37

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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

30 APR 2021 06:49:25

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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°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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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="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"/>



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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°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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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°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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 649

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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 <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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	01 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2022 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2022 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2022 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	12 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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="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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2022 23:59
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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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 <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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

**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 ☐



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

US3312291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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"/>

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

28 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

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US3312291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:58:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 07:28:49

US3312291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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

Visit date (dd MMM yyyy)	29 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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) \_\_\_\_\_

US3312291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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.*

US3312291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

09:30 (24 HR)

Collection date and time (derived)

29 MAR 2021 09:30



US3312291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 20:43:24

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312291

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 20:43:24

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3312291**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

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*

**US3312291**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Date of Contact	02 NOV 2020
Time of Contact	09:31
Date and Time of Contact (derived)	02 NOV 2020 09:31
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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"/>

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 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 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 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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"/>

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 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 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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US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 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 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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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Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 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 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) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 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 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 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 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.8 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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US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

	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"/>

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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"/>

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Date of Visit 02 NOV 2020

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

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

Date of Test 02 NOV 2020

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

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3312291

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 NOV 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)	

US3312291

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

Visit date (dd MMM yyyy)	02 NOV 2020
--------------------------	-------------

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

Folder OID	SICKD1
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US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 NOV 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 10:40
Height (xxx.x)	64 in
Weight (xxx.x)	184.9 lb
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	109 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312291

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 NOV 2020

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



US3312291

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 NOV 2020

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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) \_\_\_\_\_

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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.*

US3312291

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312291

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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

Visit date (dd MMM yyyy)	01 FEB 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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US3312291

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

Form: Unblinding

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Date of updated informed consent ( <i>dd MMM yyyy</i> )	01 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	01 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312291

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	



US3312291

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	01 FEB 2021
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 09:26
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3312291

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	01 FEB 2021
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 10:54
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3312291

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

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 FEB 2021

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

US3312291

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

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 01 FEB 2021

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

Treatment Date and Time (derived) 01 FEB 2021 10:23

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

US3312291

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 FEB 2021
Collection time (00:00-23:59)	09:16 (24 HR)
Collection date and time (derived)	01 FEB 2021 09:16

US3312291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 FEB 2021

Collection time (00:00 - 23:59)

09:15

Collection Date and Time (derived)

01 FEB 2021 09:15

US3312291

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

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312291

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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

US3312291

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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)	01 MAR 2021
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 09:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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)	01 MAR 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 10:15
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3312291

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 MAR 2021

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

US3312291

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 01 MAR 2021

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 01 MAR 2021 09:44

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

US3312291

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3312291

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312291

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312291

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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) \_\_\_\_\_

US3312291

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

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.*

US3312291

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:09:17

Generated On: 09 Jun 2021 16:58:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	29 MAR 2021 09:30

US3312291

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:54:58

Generated On: 09 Jun 2021 16:58:08

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3312291

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

AEID	
Adverse event	SORE THROAT
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)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

AEID

Adverse event

ELEVATED DIASTOLIC AND  
SYSTOLIC BLOOD PRESSURE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

09 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312291

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

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)	03 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 NOV 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 (4)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

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)	30 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)	04 NOV 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 (5)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<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) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

AEID	
Adverse event	HYPERTENSION
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)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (6)

Data signed: (b) (4) 09 Apr 2021 15:58:53

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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 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

AEID	USA-US300-2020-MRNA-1273-P30 1000025
Adverse event	CHOLECYSTITIS
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)	27 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	29 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:58:53

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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	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	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

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SUBJECT IS THE SOURCE FOR THIS SAE REPORT. 64 YR OLD WOMAN WITH H/O HTN, GERD AND INSOMNIA WHO AT HER MONTHLY PHONE CALL ON 12/21/2020 REPORTED LAPAROSCOPIC CHOLECYSTECTOMY (11/28/2020) RELATED TO CHOLECYSTITIS. REPORTS THAT WHILE IN ARIZONA OVER THANKSGIVING, BEGAN HAVING RIGHT-SIDED ABDOMINAL PAIN ON 11/27/2020. WENT TO THE ER AROUND 12:30 ON 11/28/2020 WHERE SHE WAS DIAGNOSED WITH CHOLECYSTITIS AND UNDERWENT LAPAROSCOPIC CHOLECYSTECTOMY THAT SAME DAY. WAS HOSPITALIZED POST-OPERATIVELY, OVERNIGHT, AND DISCHARGED THE NEXT THE NEXT MORNING ON 11/29/2020. SHE DENIES ANY COMPLICATIONS OR NEW MEDICATIONS RELATED TO SAE, INCLUDING NOT TAKING MEDICATION FOR PAIN CONTROL. HAS SINCE FOLLOWED UP WITH HER PCP ON 12/17/2020 WITH NO FURTHER CONCERNS. AT TIME

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:58:53

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OF CONTACT, SHE HAS  
RETURNED TO HER BASELINE  
HEALTH AND ACTIVITY. THIS IS  
AN SAE, HOSPITALIZATION  
(11/28/2020 TO 11/29/2020), NOT  
RELATED TO IP. MEDICAL  
RECORDS WILL BE REQUESTED  
UPON RECEIPT OF SIGNED  
MEDICAL RECORDS RELEASE  
FROM SUBJECT. WILL CLOSE  
SAE AFTER REVIEW OF  
MEDICAL RECORDS. UPDATE  
30MAR2021: RT-SIDED ABD PAIN  
ON NIGHT OF 27NOV2020.  
WENT TO ER AROUND 12:40 ON  
28NOV2020 C/O ABD PAIN 9/10 ,  
NAUSEA/VOMITING, NOT  
RESPONSIVE TO ALEVE,  
ALKA-SELTZER, PEPTO  
BISMOL. T98.2 HR76, RR16,  
SPO298, O2 RA, BP163/95. REC'D  
KETOROLAC 30 MG IM X1.  
WHITE COUNT WNL AT 10, LFTS  
WNL, CXR NORMAL, US  
SHOWED GALLSTONE  
IMPACTED IN INFUNDIBULUM  
WITH GALLBLADDER WALL  
THICKENING/EDEMA. CBD  
NML: 4 MM. ON EXAM, TENDER  
RUQ, POSITIVE MURPHY SIGN.  
TO OR FOR LAPAROSCOPIC  
CHOLECYSTECTOMY WITH  
INTRAOPERATIVE  
CHOLANGIOGRAM.  
TOLERATED PROCEDURE

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

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WELL, TRANSFERRED TO  
PACU,STABLE CONDITION.  
TRANSFERRED TO FLOOR FOR  
RECOVERY. DC'D IN STABLE  
CONDITION ON 29NOV2020,  
FEELING WELL, TOLERATING  
DIET, AMBULATING WITH PAIN  
CONTROLLED AND RECOMM.  
F/U WITH PCP. DENIED  
COMPLICATIONS OR NEW  
MEDS R/T SAE, INCL. NOT  
TAKING MEDS FOR PAIN  
CONTROL. FOLLOWED UP  
WITH PCP ON 17DEC2020 WITH  
NO FURTHER CONCERNS.  
RETURNED TO BASELINE  
HEALTH AND ACTIVITY. WILL  
CLOSE SAE

---

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

---

US3312291

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

AEID

Adverse event

LOWER URINARY TRACT  
INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312291

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

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



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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Relationship to Study Procedure	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Action taken with investigational product	None <input type="checkbox"/>
	Dose Delayed <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>
	Withdrawn <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="checkbox"/>
	Not Recovered/Not Resolved <input type="checkbox"/>
	Recovered/Resolved <input type="checkbox"/>
	Recovered/Resolved with Sequelae <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Unknown <input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication AMBIEN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

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 (1)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication SEASONAL INFLUENZA  
VACCINE

Prophylaxis Yes ☒  
No ☐

Indication SEASONAL INFLUENZA  
PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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)	28 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)		28 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 (4)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication LISINOPRIL/  
HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10/12.5

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 (4)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 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 (5)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication SHINGRIX

Prophylaxis Yes ☒  
No ☐

Indication SHINGLES 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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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 (6)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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="radio"/>	
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="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication (BACTRIM DS)  
SULFAMETHOXAZOLE 800MG/  
TRIMETHOPRIM 160MG

Prophylaxis Yes ☐  
No ☒

Indication LOWER URINARY TRACT  
INFECTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	Transdermal	<input type="checkbox"/>
	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 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)		16 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 (8)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication KETOROLAC

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS

Dose per administration 30

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) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	28 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication BISMUTH SBUSALICYLATE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS

Dose per administration 30

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 (9)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication ASPIRIN/CITRIC ACID/SODIUM  
BICARBONATE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS

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 (10)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 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 (11)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

Name of Medication NAPROXEN SODIUM

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:58:53

Generated On: 09 Jun 2021 16:58:08

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 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"/>



US3312291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3312291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 01:09:16

Generated On: 09 Jun 2021 16:58:08

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 NOV 2020	LAPAROSCOPIC CHOLECYSTECTOMY	Adverse Event	

US3312291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:58:08

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

US3312291

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:58:08

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 ☐

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 16:56:08

Generated On: 09 Jun 2021 16:58:08

SAEID	USA-US300-2020-MRNA-1273-P301000025
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)	5

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 16:56:08

Generated On: 09 Jun 2021 16:58:08

SAEID	USA-US300-2020-MRNA-1273-P301000025
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)	5
Date of submission (Pre-filled from custom function)	22/DEC/2020 11:57
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

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 16:56:08

Generated On: 09 Jun 2021 16:58:08

SAEID	USA-US300-2020-MRNA-1273-P301000025
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)	5
Date of submission (Pre-filled from custom function)	10/FEB/2021 09:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 16:56:08

Generated On: 09 Jun 2021 16:58:08

SAEID	USA-US300-2020-MRNA-1273-P301000025
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)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 09:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 16:56:08

Generated On: 09 Jun 2021 16:58:08

SAEID	USA-US300-2020-MRNA-1273-P301000025
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)	5
Date of submission (Pre-filled from custom function)	30/MAR/2021 14:37
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.	False

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 16:56:08

Generated On: 09 Jun 2021 16:58:08

SAEID	USA-US300-2020-MRNA-1273-P301000025
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)	5
Date of submission (Pre-filled from custom function)	31/MAR/2021 06:21
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

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (6)

Data signed: (b) (4) 09 Apr 2021 16:56:08

Generated On: 09 Jun 2021 16:58:08

SAEID	USA-US300-2020-MRNA-1273-P301000025
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)	5
Date of submission (Pre-filled from custom function)	09/APR/2021 12:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312291 (Prod: Johnson County Clin-Trials)

**US3312291**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:58:08**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'US3312291'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 14:51:22

**US3312291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:06:50

US3312291

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:58:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 14:51:23

US3312291

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:58:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	26 Aug 2020 16:06:50



**US3312291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'SCRN'	System	26 Aug 2020 16:06:50

US3312291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 14:51:25

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '63'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'YEARS'	System	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '63'	System	26 Aug 2020 16:07:02

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Female (F)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11



**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

US3312291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11

**US3312291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:08**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 15:11:11



US3312291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	Christa Estrada (b) (4)	26 Aug 2020 16:07:02

**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Aug 2020'	System	26 Aug 2020 16:07:02

**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2020'	System	26 Aug 2020 16:07:02

US3312291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Amendment 3 (3)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	27 Aug 2020 19:24:50
User entered 'Amendment 2 (2)'	(b) (4)	
	Christa Estrada (b) (4)	26 Aug 2020 16:07:02
	(b) (4)	

**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:02

**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:02

**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:02

**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4)	26 Aug 2020 16:07:02
	Christa Estrada (b) (4)	
	(b) (4)	



**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 14:51:23

**US3312291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:08**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'I'	System	26 Aug 2020 16:07:08

US3312291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:58:08

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	Christa Estrada (b) (4)	26 Aug 2020 16:07:08

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:58:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:52:34

US3312291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:58:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:54:52
Data point term sent to Coder	System	03 Sep 2020 19:53:46
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:52:55



**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2010'	System	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2010'	System	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered empty.	System	03 Sep 2020 19:52:55

**US3312291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered empty.	System	03 Sep 2020 19:52:55

US3312291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:38:47
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'verified and updated ' (Site from DM).	Karol Moore (b) (4) (b) (4)	20 Oct 2020 19:53:19
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:05:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:54:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:54:51
Data point term sent to Coder	System	03 Sep 2020 19:53:46
User entered 'hysterectomy'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:22



**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2006'	System	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2006'	System	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2006'	System	03 Sep 2020 19:53:22

**US3312291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2006'	System	03 Sep 2020 19:53:22



US3312291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:38:54
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'verified and updated per source' (Site from DM).	Karol Moore (b) (4) (b) (4)	20 Oct 2020 19:51:01
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:05:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingo-oophorectomy bilateral, LLT: Bilateral salpingo-oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:54:52
Data point term sent to Coder	System	03 Sep 2020 19:53:48
User entered 'Bilateral salpingo-oophorectomy'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2006'	System	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2006'	System	03 Sep 2020 19:53:45



**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2006'	System	03 Sep 2020 19:53:45

**US3312291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2006'	System	03 Sep 2020 19:53:45

US3312291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:55:41
Data point term sent to Coder	System	03 Sep 2020 19:54:49
User entered 'insomnia'	Karol Moore (b) (4)	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:53:57



**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2015'	System	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2015'	System	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered empty.	System	03 Sep 2020 19:53:57

**US3312291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered empty.	System	03 Sep 2020 19:53:57

US3312291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:58:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:52:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:52:38
Data point term sent to Coder	System	20 Oct 2020 19:51:11
User entered 'menorrhagia'	Karol Moore (b) (4)	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	20 Oct 2020 19:50:49



**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2006'	System	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2006'	System	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'Jan 2006'	System	20 Oct 2020 19:50:49

**US3312291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '2006'	System	20 Oct 2020 19:50:49

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39



**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '10:05'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39

**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '26 Aug 2020 10:05'	System	03 Sep 2020 19:54:39

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '64' in	(b) (4) Karol Moore (b) (4)	03 Sep 2020 19:54:39
DataPoint set to visible.	(b) (4) System	26 Aug 2020 16:07:08

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '191' lb	(b) (4) Karol Moore (b) (4)	03 Sep 2020 19:54:39
DataPoint set to visible.	(b) (4) System	26 Aug 2020 16:07:08

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered '32.85363'	System	03 Sep 2020 19:54:39
DataPoint set to visible.	System	26 Aug 2020 16:07:08

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'kg/m2'	System	03 Sep 2020 19:54:39
DataPoint set to visible.	System	26 Aug 2020 16:07:08

**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39



US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39

**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39

**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'bpm'	System	03 Sep 2020 19:54:39

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	03 Sep 2020 19:54:39

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'breaths/min'	System	03 Sep 2020 19:54:39

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:39

US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'mmHg'	System	03 Sep 2020 19:54:39

**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	03 Sep 2020 19:54:39



US3312291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User entered 'mmHg'	System	03 Sep 2020 19:54:39

**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15

**US3312291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15

**US3312291**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:47

**US3312291**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:54:47

**US3312291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:58:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06

US3312291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:58:08

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06

US3312291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:58:08

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 08:45:23
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'updated on mh' (Site from DM).	Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:13:30
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 10:54:15
User entered 'Surgically sterile (SURGICALLY STERILE)'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06



**US3312291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:58:08**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06

US3312291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06

**US3312291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:58:08**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06

US3312291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06

**US3312291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:58:08**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:06

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38



US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

[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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38



**US3312291**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:58:08**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

**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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

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 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38



US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

US3312291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:21:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:55:38

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:19

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:19

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[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 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	26 Aug 2020 16:07:19

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'VISIT1'	System	26 Aug 2020 16:07:19

US3312291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 15:45:48

US3312291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:08

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '108440'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 15:45:48



US3312291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:08

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 15:45:48

US3312291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:08

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 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	Christa Estrada (b) (4)	26 Aug 2020 16:07:33

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:58:08**

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 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	Christa Estrada (b) (4)	26 Aug 2020 16:07:33

US3312291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:08

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:33

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:58:08**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:33

US3312291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:33

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:58:08**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 18:18:26
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:01:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:01:38

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56



**US3312291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	03 Sep 2020 19:56:56
	(b) (4)	

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '10:05'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered '26 Aug 2020 10:05'	System	03 Sep 2020 19:56:56



US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '98.3' F	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '70'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'bpm'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'breaths/min'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '140'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56



US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'mmHg'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '79'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'mmHg'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	03 Sep 2020 19:57:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	03 Sep 2020 19:57:18
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	03 Sep 2020 19:56:56
User entered 'No (N)'	System	03 Sep 2020 19:56:56
	Karol Moore (b) (4)	03 Sep 2020 19:56:56
	(b) (4)	

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56



US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:34:10
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:40:54
User entered '11:34'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered '26 Aug 2020 11:34'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '98.3' F	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '70'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'bpm'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56



US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'breaths/min'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '140'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'mmHg'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '78'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'mmHg'	System	03 Sep 2020 19:56:56

US3312291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:25

US3312291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:25

US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:59



US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:59

US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

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 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	Christa Estrada (b) (4)	26 Aug 2020 16:07:59

US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 16:07:59

US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:59

US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '11:03'	(b) (4) Christa Estrada (b) (4)	26 Aug 2020 16:07:59

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered '26 Aug 2020 11:03'	System	26 Aug 2020 16:07:59

US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	26 Aug 2020 16:07:59

US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'ONCE'	System	26 Aug 2020 16:07:59



US3312291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 16:07:59

US3312291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:37

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:37

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '10:33'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:37

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered '26 Aug 2020 10:33'	System	03 Sep 2020 19:57:37

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 16:58:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:46

US3312291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:46

US3312291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:46



**US3312291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:08**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '10:26'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:46

**US3312291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered '26 Aug 2020 10:26'	System	03 Sep 2020 19:57:46

US3312291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:46

US3312291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:46

US3312291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:46

US3312291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered empty.	System	03 Sep 2020 19:57:46

US3312291

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:58:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:57:49

US3312291

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:58:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'I'	System	03 Sep 2020 19:57:49



US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:34:58', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb2c8949-bd97-4949-9e26-095c8b329421' User entered 'Yes (Y)'	System	26 Aug 2020 16:35:20
	System	26 Aug 2020 16:35:20

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:05', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb2c8949-bd97-4949-9e26-095c8b329421' User entered '98.3'	System	26 Aug 2020 16:35:20
	System	26 Aug 2020 16:35:20

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:09', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb2c8949-bd97-4949-9e26-095c8b329421' User entered 'No (N)'	System	26 Aug 2020 16:35:20
	System	26 Aug 2020 16:35:20

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb2c8949-bd97-4949-9e26-095c8b329421' User entered '26 Aug 2020 11:35'	System	26 Aug 2020 16:35:20
	System	26 Aug 2020 16:35:20

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 11:23'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 13:53'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:21', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f40c1f9d-d2ff-408d-95d4-0435dc9d1fb6' User entered 'Yes (Y)'	System	27 Aug 2020 04:26:45
	System	27 Aug 2020 04:26:45

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:30', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f40c1f9d-d2ff-408d-95d4-0435dc9d1fb6' User entered '98.7'	System	27 Aug 2020 04:26:45
	System	27 Aug 2020 04:26:45

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f40c1f9d-d2ff-408d-95d4-0435dc9d1fb6'	System	27 Aug 2020 04:26:45
User entered 'No (N)'	System	27 Aug 2020 04:26:45

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f40c1f9d-d2ff-408d-95d4-0435dc9d1fb6' User entered '26 Aug 2020 23:26'	System	27 Aug 2020 04:26:45
	System	27 Aug 2020 04:26:45

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 14:48'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 2'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:02:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '12c07265-7257-46ae-b819-39bd65736d3d' User entered 'Yes (Y)'	System	27 Aug 2020 17:03:49
	System	27 Aug 2020 17:03:49



US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:02:50', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '12c07265-7257-46ae-b819-39bd65736d3d' User entered '96.3'	System	27 Aug 2020 17:03:49
	System	27 Aug 2020 17:03:49

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:02:53', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '12c07265-7257-46ae-b819-39bd65736d3d' User entered 'No (N)'	System	27 Aug 2020 17:03:49
	System	27 Aug 2020 17:03:49

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:02', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '12c07265-7257-46ae-b819-39bd65736d3d' User entered '27 Aug 2020 12:03'	System	27 Aug 2020 17:03:49
	System	27 Aug 2020 17:03:49

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 3'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:21:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '87aac3b5-a942-4a11-9a78-d98395738b35' User entered 'Yes (Y)'	System	29 Aug 2020 00:22:08
	System	29 Aug 2020 00:22:08

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:21:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '87aac3b5-a942-4a11-9a78-d98395738b35' User entered '96.7'	System	29 Aug 2020 00:22:08
	System	29 Aug 2020 00:22:08



US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:21:59', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '87aac3b5-a942-4a11-9a78-d98395738b35' User entered 'No (N)'	System	29 Aug 2020 00:22:08
	System	29 Aug 2020 00:22:08

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:01', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '87aac3b5-a942-4a11-9a78-d98395738b35' User entered '28 Aug 2020 19:22'	System	29 Aug 2020 00:22:08
	System	29 Aug 2020 00:22:08

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 4'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:27', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c2710177-aa26-4d8a-b751-502cc2c33b25'	System	29 Aug 2020 17:14:45
User entered 'Yes (Y)'	System	29 Aug 2020 17:14:45

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c2710177-aa26-4d8a-b751-502cc2c33b25' User entered '96.7'	System	29 Aug 2020 17:14:45
	System	29 Aug 2020 17:14:45

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:35', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c2710177-aa26-4d8a-b751-502cc2c33b25'	System	29 Aug 2020 17:14:45
User entered 'No (N)'	System	29 Aug 2020 17:14:45



**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:42', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c2710177-aa26-4d8a-b751-502cc2c33b25' User entered '29 Aug 2020 12:14'	System	29 Aug 2020 17:14:45
	System	29 Aug 2020 17:14:45

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 5'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:42', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '7e342b43-73e9-4d72-a3bf-b01d6f760c9f' User entered 'Yes (Y)'	System	30 Aug 2020 21:25:50
	System	30 Aug 2020 21:25:50

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:36', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '7e342b43-73e9-4d72-a3bf-b01d6f760c9f' User entered '96.6'	System	30 Aug 2020 21:25:50
	System	30 Aug 2020 21:25:50

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '7e342b43-73e9-4d72-a3bf-b01d6f760c9f' User entered 'No (N)'	System	30 Aug 2020 21:25:50
	System	30 Aug 2020 21:25:50

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:45', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '7e342b43-73e9-4d72-a3bf-b01d6f760c9f' User entered '30 Aug 2020 16:25'	System	30 Aug 2020 21:25:50
	System	30 Aug 2020 21:25:50



US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 6'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8222cd06-0add-407f-996e-543f5de9db81' User entered 'Yes (Y)'	System	31 Aug 2020 18:41:30
	System	31 Aug 2020 18:41:30

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8222cd06-0add-407f-996e-543f5de9db81' User entered '96.7'	System	31 Aug 2020 18:41:30
	System	31 Aug 2020 18:41:30

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:24', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8222cd06-0add-407f-996e-543f5de9db81' User entered 'No (N)'	System	31 Aug 2020 18:41:30
	System	31 Aug 2020 18:41:30

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:28', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8222cd06-0add-407f-996e-543f5de9db81' User entered '31 Aug 2020 13:41'	System	31 Aug 2020 18:41:30
	System	31 Aug 2020 18:41:30

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 7'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:17:12', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c4001378-127b-40da-9425-7029282ee1f9' User entered 'Yes (Y)'	System	01 Sep 2020 18:17:52
	System	01 Sep 2020 18:17:52

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:17:42', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c4001378-127b-40da-9425-7029282ee1f9' User entered '96.6'	System	01 Sep 2020 18:17:52
	System	01 Sep 2020 18:17:52

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:17:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c4001378-127b-40da-9425-7029282ee1f9' User entered 'No (N)'	System	01 Sep 2020 18:17:52
	System	01 Sep 2020 18:17:52

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:17:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c4001378-127b-40da-9425-7029282ee1f9' User entered '01 Sep 2020 13:17'	System	01 Sep 2020 18:17:52
	System	01 Sep 2020 18:17:52

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:24', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e048c997-3eb0-4ac3-83a7-4da6a3a10fa7'	System	26 Aug 2020 16:35:54
User entered 'None (1)'	System	26 Aug 2020 16:35:54

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:29', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e048c997-3eb0-4ac3-83a7-4da6a3a10fa7' User entered 'No (N)'	System	26 Aug 2020 16:35:54
	System	26 Aug 2020 16:35:54

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e048c997-3eb0-4ac3-83a7-4da6a3a10fa7' User entered 'No (N)'	System	26 Aug 2020 16:35:54
	System	26 Aug 2020 16:35:54

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e048c997-3eb0-4ac3-83a7-4da6a3a10fa7' User entered 'None (1)'	System	26 Aug 2020 16:35:54
	System	26 Aug 2020 16:35:54

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:52', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e048c997-3eb0-4ac3-83a7-4da6a3a10fa7' User entered '26 Aug 2020 11:35'	System	26 Aug 2020 16:35:54
	System	26 Aug 2020 16:35:54

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 11:23'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 13:53'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '5fe55a9a-8120-44d8-9af2-0dcea2f982a6' User entered 'None (1)'	System	27 Aug 2020 04:27:04
	System	27 Aug 2020 04:27:04

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:48', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '5fe55a9a-8120-44d8-9af2-0dcea2f982a6' User entered 'No (N)'	System	27 Aug 2020 04:27:04
	System	27 Aug 2020 04:27:04

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '5fe55a9a-8120-44d8-9af2-0dcea2f982a6' User entered 'No (N)'	System	27 Aug 2020 04:27:04
	System	27 Aug 2020 04:27:04

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:57', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '5fe55a9a-8120-44d8-9af2-0dcea2f982a6' User entered 'None (1)'	System	27 Aug 2020 04:27:04
	System	27 Aug 2020 04:27:04

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:26:59', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '5fe55a9a-8120-44d8-9af2-0dcea2f982a6' User entered '26 Aug 2020 23:26'	System	27 Aug 2020 04:27:04
	System	27 Aug 2020 04:27:04

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 14:48'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 2'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:07', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '442eebc7-4756-4170-9761-4cb4a8896302'	System	27 Aug 2020 17:04:10
User entered 'None (1)'	System	27 Aug 2020 17:04:10

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:10', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '442eebc7-4756-4170-9761-4cb4a8896302' User entered 'No (N)'	System	27 Aug 2020 17:04:10
	System	27 Aug 2020 17:04:10

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:17', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '442eebc7-4756-4170-9761-4cb4a8896302' User entered 'No (N)'	System	27 Aug 2020 17:04:10
	System	27 Aug 2020 17:04:10

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:24', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '442eebc7-4756-4170-9761-4cb4a8896302'	System	27 Aug 2020 17:04:10
User entered 'None (1)'	System	27 Aug 2020 17:04:10

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:28', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '442eebc7-4756-4170-9761-4cb4a8896302' User entered '27 Aug 2020 12:03'	System	27 Aug 2020 17:04:10
	System	27 Aug 2020 17:04:10

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 3'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:12', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '99929a49-0d89-49e9-8705-259fa3e7dde7'	System	29 Aug 2020 00:22:28
User entered 'None (1)'	System	29 Aug 2020 00:22:28

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:11', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '99929a49-0d89-49e9-8705-259fa3e7dde7'	System	29 Aug 2020 00:22:28
User entered 'No (N)'	System	29 Aug 2020 00:22:28

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:14', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '99929a49-0d89-49e9-8705-259fa3e7dde7'	System	29 Aug 2020 00:22:28
User entered 'No (N)'	System	29 Aug 2020 00:22:28

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:19', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '99929a49-0d89-49e9-8705-259fa3e7dde7'	System	29 Aug 2020 00:22:28
User entered 'None (1)'	System	29 Aug 2020 00:22:28

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:22', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '99929a49-0d89-49e9-8705-259fa3e7dde7' User entered '28 Aug 2020 19:22'	System	29 Aug 2020 00:22:28
	System	29 Aug 2020 00:22:28

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 4'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:47', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dcd81fdf-4b2c-4cfc-a901-f0eb186a9724'	System	29 Aug 2020 17:15:06
User entered 'None (1)'	System	29 Aug 2020 17:15:06

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:50', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dcd81fdf-4b2c-4cfc-a901-f0eb186a9724'	System	29 Aug 2020 17:15:06
User entered 'No (N)'	System	29 Aug 2020 17:15:06

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:53', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dcd81fdf-4b2c-4cfc-a901-f0eb186a9724'	System	29 Aug 2020 17:15:06
User entered 'No (N)'	System	29 Aug 2020 17:15:06

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:14:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dcd81fdf-4b2c-4cfc-a901-f0eb186a9724' User entered 'None (1)'	System	29 Aug 2020 17:15:06
	System	29 Aug 2020 17:15:06

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dcd81fdf-4b2c-4cfc-a901-f0eb186a9724' User entered '29 Aug 2020 12:15'	System	29 Aug 2020 17:15:06
	System	29 Aug 2020 17:15:06

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 5'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'cab0c18f-be01-4566-a006-ceec57c45441' User entered 'None (1)'	System	30 Aug 2020 21:26:07
	System	30 Aug 2020 21:26:07

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:53', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'cab0c18f-be01-4566-a006-ceec57c45441' User entered 'No (N)'	System	30 Aug 2020 21:26:07
	System	30 Aug 2020 21:26:07

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'cab0c18f-be01-4566-a006-ceec57c45441' User entered 'No (N)'	System	30 Aug 2020 21:26:07
	System	30 Aug 2020 21:26:07

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:25:58', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'cab0c18f-be01-4566-a006-ceec57c45441' User entered 'None (1)'	System	30 Aug 2020 21:26:07
	System	30 Aug 2020 21:26:07

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:02', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'cab0c18f-be01-4566-a006-ceec57c45441' User entered '30 Aug 2020 16:26'	System	30 Aug 2020 21:26:07
	System	30 Aug 2020 21:26:07

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 6'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f10584ff-fefc-4f3e-ac16-cf103892cd7f' User entered 'None (1)'	System	31 Aug 2020 18:41:48
	System	31 Aug 2020 18:41:48

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f10584ff-fefc-4f3e-ac16-cf103892cd7f' User entered 'No (N)'	System	31 Aug 2020 18:41:48
	System	31 Aug 2020 18:41:48

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:38', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f10584ff-fefc-4f3e-ac16-cf103892cd7f' User entered 'No (N)'	System	31 Aug 2020 18:41:48
	System	31 Aug 2020 18:41:48

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:40', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f10584ff-fefc-4f3e-ac16-cf103892cd7f' User entered 'None (1)'	System	31 Aug 2020 18:41:48
	System	31 Aug 2020 18:41:48

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f10584ff-fefc-4f3e-ac16-cf103892cd7f' User entered '31 Aug 2020 13:41'	System	31 Aug 2020 18:41:48
	System	31 Aug 2020 18:41:48

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 7'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:17:52', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1569028-e232-4aaa-9947-06c454bfc6c'	System	01 Sep 2020 18:18:08
User entered 'None (1)'	System	01 Sep 2020 18:18:08

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:17:57', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1569028-e232-4aaa-9947-06c454bfcb6c' User entered 'No (N)'	System	01 Sep 2020 18:18:08
	System	01 Sep 2020 18:18:08

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:17:59', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1569028-e232-4aaa-9947-06c454bfc6c'	System	01 Sep 2020 18:18:08
User entered 'No (N)'	System	01 Sep 2020 18:18:08

US3312291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:03', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1569028-e232-4aaa-9947-06c454bfc6c'	System	01 Sep 2020 18:18:08
User entered 'None (1)'	System	01 Sep 2020 18:18:08

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:05', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1569028-e232-4aaa-9947-06c454bfc6c'	System	01 Sep 2020 18:18:08
User entered '01 Sep 2020 13:18'	System	01 Sep 2020 18:18:08

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:07:59



**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:35:58', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb' User entered 'None (0)'	System	26 Aug 2020 16:36:38
	System	26 Aug 2020 16:36:38

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:36:01', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb' User entered 'None (0)'	System	26 Aug 2020 16:36:38
	System	26 Aug 2020 16:36:38

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:36:06', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb' User entered 'None (0)'	System	26 Aug 2020 16:36:38
	System	26 Aug 2020 16:36:38

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:36:10', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb' User entered 'None (0)'	System	26 Aug 2020 16:36:38
	System	26 Aug 2020 16:36:38

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:36:17', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb' User entered 'None (0)'	System	26 Aug 2020 16:36:38
	System	26 Aug 2020 16:36:38

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:36:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb' User entered 'None (0)'	System	26 Aug 2020 16:36:38
	System	26 Aug 2020 16:36:38

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:36:29', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb'	System	26 Aug 2020 16:36:38
User entered 'No (N)'	System	26 Aug 2020 16:36:38



**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T11:36:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '969362fc-fd5e-4fe7-976d-3f0b39b5d9bb' User entered '26 Aug 2020 11:36'	System	26 Aug 2020 16:36:38
	System	26 Aug 2020 16:36:38

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 11:23'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 13:53'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:05', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7' User entered 'None (0)'	System	27 Aug 2020 04:27:28
	System	27 Aug 2020 04:27:28

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7' User entered 'None (0)'	System	27 Aug 2020 04:27:28
	System	27 Aug 2020 04:27:28

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:10', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7' User entered 'None (0)'	System	27 Aug 2020 04:27:28
	System	27 Aug 2020 04:27:28

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:13', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7' User entered 'None (0)'	System	27 Aug 2020 04:27:28
	System	27 Aug 2020 04:27:28



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7'	System	27 Aug 2020 04:27:28
User entered 'None (0)'	System	27 Aug 2020 04:27:28

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:19', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7' User entered 'None (0)'	System	27 Aug 2020 04:27:28
	System	27 Aug 2020 04:27:28

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:22', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7'	System	27 Aug 2020 04:27:28
User entered 'No (N)'	System	27 Aug 2020 04:27:28

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-26T23:27:25', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '386d5756-9184-4575-88ed-010f5c4463b7'	System	27 Aug 2020 04:27:28
User entered '26 Aug 2020 23:27'	System	27 Aug 2020 04:27:28

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Aug 2020 14:48'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 2'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered 'None (0)'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered 'None (0)'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:37', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered 'None (0)'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:45', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered 'None (0)'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:47', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered 'None (0)'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered 'None (0)'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:54', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered 'No (N)'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-27T12:03:58', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e338bec2-4b8f-4f8c-a022-8ae95b56b8dc' User entered '27 Aug 2020 12:03'	System	27 Aug 2020 17:04:20
	System	27 Aug 2020 17:04:20

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 3'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:26', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered 'None (0)'	System	29 Aug 2020 00:22:50

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:28', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered 'None (0)'	System	29 Aug 2020 00:22:50

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered 'None (0)'	System	29 Aug 2020 00:22:50

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:35', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered 'None (0)'	System	29 Aug 2020 00:22:50

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:37', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered 'None (0)'	System	29 Aug 2020 00:22:50

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered 'None (0)'	System	29 Aug 2020 00:22:50



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:43', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered 'No (N)'	System	29 Aug 2020 00:22:50

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-28T19:22:45', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '16ea3fee-5f5d-42bc-a9cc-c9be8231e558'	System	29 Aug 2020 00:22:50
User entered '28 Aug 2020 19:22'	System	29 Aug 2020 00:22:50

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 4'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:04', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered 'None (0)'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:06', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered 'None (0)'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered 'None (0)'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:10', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered 'None (0)'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:12', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered 'None (0)'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:14', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered 'None (0)'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:17', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered 'No (N)'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-29T12:15:21', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '017de8e6-e115-4913-a2ec-8cc149c7c873' User entered '29 Aug 2020 12:15'	System	29 Aug 2020 17:15:24
	System	29 Aug 2020 17:15:24

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 5'	System	26 Aug 2020 16:07:59



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:10', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered 'None (0)'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:11', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered 'None (0)'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:14', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered 'None (0)'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered 'None (0)'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:19', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered 'None (0)'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:21', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered 'None (0)'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:23', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered 'No (N)'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-30T16:26:25', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '4ca52a49-9a3d-47fd-9c25-060704ad27e1' User entered '30 Aug 2020 16:26'	System	30 Aug 2020 21:26:27
	System	30 Aug 2020 21:26:27



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 6'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:50', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0' User entered 'None (0)'	System	31 Aug 2020 18:42:08
	System	31 Aug 2020 18:42:08

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0' User entered 'None (0)'	System	31 Aug 2020 18:42:08
	System	31 Aug 2020 18:42:08

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:54', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0' User entered 'None (0)'	System	31 Aug 2020 18:42:08
	System	31 Aug 2020 18:42:08

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0' User entered 'None (0)'	System	31 Aug 2020 18:42:08
	System	31 Aug 2020 18:42:08

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:57', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0' User entered 'None (0)'	System	31 Aug 2020 18:42:08
	System	31 Aug 2020 18:42:08



**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:41:59', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0' User entered 'None (0)'	System	31 Aug 2020 18:42:08
	System	31 Aug 2020 18:42:08

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:42:01', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0'	System	31 Aug 2020 18:42:08
User entered 'No (N)'	System	31 Aug 2020 18:42:08

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-08-31T13:42:04', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f8241c77-9599-4d5b-931e-e322288a42f0' User entered '31 Aug 2020 13:42'	System	31 Aug 2020 18:42:08
	System	31 Aug 2020 18:42:08

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 7'	System	26 Aug 2020 16:07:59

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:09', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered 'None (0)'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:10', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered 'None (0)'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26



US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:12', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered 'None (0)'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:14', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered 'None (0)'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered 'None (0)'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:18', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered 'None (0)'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26

US3312291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered 'No (N)'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-01T13:18:22', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '061048ec-b41c-4307-b65b-ad6b96f7d72f' User entered '01 Sep 2020 13:18'	System	01 Sep 2020 18:18:26
	System	01 Sep 2020 18:18:26

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:07:59

**US3312291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:07:59



**US3312291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:58:05

**US3312291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '2 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:58:05

**US3312291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:58:05

US3312291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4)	03 Sep 2020 19:58:05
	Karol Moore (b) (4)	
	(b) (4)	

US3312291

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:58:08

**US3312291**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'I'	System	03 Sep 2020 19:58:08

**US3312291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:11:45

**US3312291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:11:45



**US3312291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:11:45

**US3312291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4)	17 Sep 2020 20:11:45
	Karol Moore (b) (4)	
	(b) (4)	

**US3312291**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:11:51

**US3312291**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:57
User entered 'I'	System	17 Sep 2020 20:11:51

**US3312291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:49
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 20:12:03
	Karol Moore (b) (4)	
	(b) (4)	

**US3312291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:49
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '16 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:12:03

**US3312291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:49
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:12:03

**US3312291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:49
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4)	17 Sep 2020 20:12:03
	Karol Moore (b) (4)	
	(b) (4)	



**US3312291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:49
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 20:12:07
	Karol Moore (b) (4)	
	(b) (4)	

**US3312291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:49
User entered 'I'	System	17 Sep 2020 20:12:07

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:29:56

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:29:56

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:29:56

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'VISIT2'	System	23 Sep 2020 18:29:56

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38



US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '23 Sep 2020'	(b) (4)	08 Oct 2020 23:18:38
	Karol Moore (b) (4)	
	(b) (4)	

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '12:33'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered '23 Sep 2020 12:33'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '97.8' F	(b) (4)	08 Oct 2020 23:18:38
	Karol Moore (b) (4)	
	(b) (4)	

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '63'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'bpm'	System	08 Oct 2020 23:18:38



**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'breaths/min'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '156'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'mmHg'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '80'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'mmHg'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38



US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '13:54'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered '23 Sep 2020 13:54'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '98.2' F	(b) (4)	08 Oct 2020 23:18:38
	Karol Moore (b) (4)	
	(b) (4)	

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '63'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'bpm'	System	08 Oct 2020 23:18:38



**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'breaths/min'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '132'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'mmHg'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '75'	(b) (4)	08 Oct 2020 23:18:38
	Karol Moore (b) (4)	
	(b) (4)	

US3312291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'mmHg'	System	08 Oct 2020 23:18:38

US3312291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:45

US3312291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:45



US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User closed query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:41:16
Query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:18:54
User opened query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 02:34:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 18:30:16

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:30:16

US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

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)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:30:16

US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 18:30:16

US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:30:16

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '13:23'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:30:16

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered '23 Sep 2020 13:23'	System	23 Sep 2020 18:30:16

US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:30:16



US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'ONCE'	System	23 Sep 2020 18:30:16

US3312291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 18:30:16

US3312291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:03

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:03

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '12:57'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:03

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered '23 Sep 2020 12:57'	System	08 Oct 2020 23:19:03

US3312291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:58:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:12

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:12



**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:12

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '12:54'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:12

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered '23 Sep 2020 12:54'	System	08 Oct 2020 23:19:12

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:12

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:12

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:19:12

**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered empty.	System	08 Oct 2020 23:19:12

US3312291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:30:24



**US3312291**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'I'	System	23 Sep 2020 18:30:24

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:13', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '24933cc5-3c32-452b-aea2-8859dbc0792c' User entered 'Yes (Y)'	System	23 Sep 2020 18:59:31
	System	23 Sep 2020 18:59:31

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:21', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '24933cc5-3c32-452b-aea2-8859dbc0792c' User entered '98.2'	System	23 Sep 2020 18:59:31
	System	23 Sep 2020 18:59:31

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:24', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '24933cc5-3c32-452b-aea2-8859dbc0792c' User entered 'No (N)'	System	23 Sep 2020 18:59:31
	System	23 Sep 2020 18:59:31

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:28', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '24933cc5-3c32-452b-aea2-8859dbc0792c' User entered '23 Sep 2020 13:59'	System	23 Sep 2020 18:59:31
	System	23 Sep 2020 18:59:31

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 13:43'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 16:13'	System	23 Sep 2020 18:30:16



US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:15:29', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6b6783d5-fc0f-44a4-b8d4-744f71cf3212'	System	24 Sep 2020 02:15:45
User entered 'Yes (Y)'	System	24 Sep 2020 02:15:45

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:15:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6b6783d5-fc0f-44a4-b8d4-744f71cf3212' User entered '98.2'	System	24 Sep 2020 02:15:45
	System	24 Sep 2020 02:15:45

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:15:37', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6b6783d5-fc0f-44a4-b8d4-744f71cf3212'	System	24 Sep 2020 02:15:45
User entered 'No (N)'	System	24 Sep 2020 02:15:45

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:15:41', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6b6783d5-fc0f-44a4-b8d4-744f71cf3212'	System	24 Sep 2020 02:15:45
User entered '23 Sep 2020 21:15'	System	24 Sep 2020 02:15:45

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 17:08'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 2'	System	23 Sep 2020 18:30:16



US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '678192e9-3b75-4793-af59-f910ff483e3b' User entered 'Yes (Y)'	System	25 Sep 2020 14:35:43
	System	25 Sep 2020 14:35:43

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:30', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '678192e9-3b75-4793-af59-f910ff483e3b' User entered '96.8'	System	25 Sep 2020 14:35:43
	System	25 Sep 2020 14:35:43

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:33', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '678192e9-3b75-4793-af59-f910ff483e3b' User entered 'No (N)'	System	25 Sep 2020 14:35:43
	System	25 Sep 2020 14:35:43

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:38', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '678192e9-3b75-4793-af59-f910ff483e3b' User entered '25 Sep 2020 09:35'	System	25 Sep 2020 14:35:43
	System	25 Sep 2020 14:35:43

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 3'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:21:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb05248b-2c7c-4788-9147-cc84c3fb4eb1' User entered 'Yes (Y)'	System	25 Sep 2020 18:21:51
	System	25 Sep 2020 18:21:51



US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:21:41', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb05248b-2c7c-4788-9147-cc84c3fb4eb1' User entered '97.3'	System	25 Sep 2020 18:21:51
	System	25 Sep 2020 18:21:51

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:21:45', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb05248b-2c7c-4788-9147-cc84c3fb4eb1' User entered 'No (N)'	System	25 Sep 2020 18:21:51
	System	25 Sep 2020 18:21:51

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:21:47', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'fb05248b-2c7c-4788-9147-cc84c3fb4eb1' User entered '25 Sep 2020 13:21'	System	25 Sep 2020 18:21:51
	System	25 Sep 2020 18:21:51

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 4'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '3ea0e1b6-f546-4a8a-b21f-08088bb45544'	System	26 Sep 2020 20:32:33
User entered 'Yes (Y)'	System	26 Sep 2020 20:32:33

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:24', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '3ea0e1b6-f546-4a8a-b21f-08088bb45544' User entered '97.3'	System	26 Sep 2020 20:32:33
	System	26 Sep 2020 20:32:33



US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:27', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '3ea0e1b6-f546-4a8a-b21f-08088bb45544'	System	26 Sep 2020 20:32:33
User entered 'No (N)'	System	26 Sep 2020 20:32:33

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:29', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '3ea0e1b6-f546-4a8a-b21f-08088bb45544' User entered '26 Sep 2020 15:32'	System	26 Sep 2020 20:32:33
	System	26 Sep 2020 20:32:33

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 5'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:03:38', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '726c6116-fce6-46af-b232-23ecec1d862a' User entered 'Yes (Y)'	System	27 Sep 2020 21:03:54
	System	27 Sep 2020 21:03:54

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:03:43', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '726c6116-fce6-46af-b232-23ecec1d862a' User entered '97.3'	System	27 Sep 2020 21:03:54
	System	27 Sep 2020 21:03:54

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:03:47', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '726c6116-fce6-46af-b232-23ecec1d862a' User entered 'No (N)'	System	27 Sep 2020 21:03:54
	System	27 Sep 2020 21:03:54



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:03:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '726c6116-fce6-46af-b232-23ecec1d862a' User entered '27 Sep 2020 16:03'	System	27 Sep 2020 21:03:54
	System	27 Sep 2020 21:03:54

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 6'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:23', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '0c8f5839-83d8-47a6-9d00-d4a05a8638fc' User entered 'Yes (Y)'	System	28 Sep 2020 20:51:38
	System	28 Sep 2020 20:51:38

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:29', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '0c8f5839-83d8-47a6-9d00-d4a05a8638fc' User entered '96.7'	System	28 Sep 2020 20:51:38
	System	28 Sep 2020 20:51:38

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '0c8f5839-83d8-47a6-9d00-d4a05a8638fc' User entered 'No (N)'	System	28 Sep 2020 20:51:38
	System	28 Sep 2020 20:51:38

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:36', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '0c8f5839-83d8-47a6-9d00-d4a05a8638fc' User entered '28 Sep 2020 15:51'	System	28 Sep 2020 20:51:38
	System	28 Sep 2020 20:51:38



US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 7'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:13', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '42292155-8e68-4692-93b6-6c2947f4ec19' User entered 'Yes (Y)'	System	30 Sep 2020 10:20:27
	System	30 Sep 2020 10:20:27

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:19', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '42292155-8e68-4692-93b6-6c2947f4ec19' User entered '97.3'	System	30 Sep 2020 10:20:27
	System	30 Sep 2020 10:20:27

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:21', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '42292155-8e68-4692-93b6-6c2947f4ec19' User entered 'No (N)'	System	30 Sep 2020 10:20:27
	System	30 Sep 2020 10:20:27

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:24', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '42292155-8e68-4692-93b6-6c2947f4ec19' User entered '30 Sep 2020 05:20'	System	30 Sep 2020 10:20:27
	System	30 Sep 2020 10:20:27

US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



US3312291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '51a11dbd-12b1-469a-a077-3b03a93e3bf4' User entered 'None (1)'	System	23 Sep 2020 18:59:52
	System	23 Sep 2020 18:59:52

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '51a11dbd-12b1-469a-a077-3b03a93e3bf4' User entered 'No (N)'	System	23 Sep 2020 18:59:52
	System	23 Sep 2020 18:59:52

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:43', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '51a11dbd-12b1-469a-a077-3b03a93e3bf4' User entered 'No (N)'	System	23 Sep 2020 18:59:52
	System	23 Sep 2020 18:59:52

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '51a11dbd-12b1-469a-a077-3b03a93e3bf4' User entered 'None (1)'	System	23 Sep 2020 18:59:52
	System	23 Sep 2020 18:59:52

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:48', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '51a11dbd-12b1-469a-a077-3b03a93e3bf4' User entered '23 Sep 2020 13:59'	System	23 Sep 2020 18:59:52
	System	23 Sep 2020 18:59:52

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 13:43'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 16:13'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:15:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'ae171092-aad9-44dc-aeec-b661f36c4c5d' User entered 'None (1)'	System	24 Sep 2020 02:16:14
	System	24 Sep 2020 02:16:14

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:15:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'ae171092-aad9-44dc-aeec-b661f36c4c5d' User entered 'No (N)'	System	24 Sep 2020 02:16:14
	System	24 Sep 2020 02:16:14

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:15:53', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'ae171092-aad9-44dc-aeec-b661f36c4c5d' User entered 'No (N)'	System	24 Sep 2020 02:16:14
	System	24 Sep 2020 02:16:14

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:07', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'ae171092-aad9-44dc-aeec-b661f36c4c5d' User entered 'None (1)'	System	24 Sep 2020 02:16:14
	System	24 Sep 2020 02:16:14

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:09', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'ae171092-aad9-44dc-aeec-b661f36c4c5d' User entered '23 Sep 2020 21:16'	System	24 Sep 2020 02:16:14
	System	24 Sep 2020 02:16:14

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 17:08'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 2'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:42', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bf15c486-d40b-41df-a088-5f72c003f6ce' User entered 'None (1)'	System	25 Sep 2020 14:35:55
	System	25 Sep 2020 14:35:55

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bf15c486-d40b-41df-a088-5f72c003f6ce' User entered 'No (N)'	System	25 Sep 2020 14:35:55
	System	25 Sep 2020 14:35:55

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:48', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bf15c486-d40b-41df-a088-5f72c003f6ce' User entered 'No (N)'	System	25 Sep 2020 14:35:55
	System	25 Sep 2020 14:35:55

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:50', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bf15c486-d40b-41df-a088-5f72c003f6ce' User entered 'None (1)'	System	25 Sep 2020 14:35:55
	System	25 Sep 2020 14:35:55

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:52', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bf15c486-d40b-41df-a088-5f72c003f6ce' User entered '25 Sep 2020 09:35'	System	25 Sep 2020 14:35:55
	System	25 Sep 2020 14:35:55

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 3'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:21:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd2b920cd-9cda-46a7-bd09-1d820cad9036'	System	25 Sep 2020 18:22:10
User entered 'None (1)'	System	25 Sep 2020 18:22:10

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:21:57', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd2b920cd-9cda-46a7-bd09-1d820cad9036' User entered 'No (N)'	System	25 Sep 2020 18:22:10
	System	25 Sep 2020 18:22:10

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd2b920cd-9cda-46a7-bd09-1d820cad9036' User entered 'No (N)'	System	25 Sep 2020 18:22:10
	System	25 Sep 2020 18:22:10

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:05', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd2b920cd-9cda-46a7-bd09-1d820cad9036'	System	25 Sep 2020 18:22:10
User entered 'None (1)'	System	25 Sep 2020 18:22:10

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd2b920cd-9cda-46a7-bd09-1d820cad9036' User entered '25 Sep 2020 13:22'	System	25 Sep 2020 18:22:10
	System	25 Sep 2020 18:22:10

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 4'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '651e21ce-a148-4ac6-96fb-90b988c6a765' User entered 'None (1)'	System	26 Sep 2020 20:32:48
	System	26 Sep 2020 20:32:48

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:36', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '651e21ce-a148-4ac6-96fb-90b988c6a765' User entered 'No (N)'	System	26 Sep 2020 20:32:48
	System	26 Sep 2020 20:32:48

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '651e21ce-a148-4ac6-96fb-90b988c6a765' User entered 'No (N)'	System	26 Sep 2020 20:32:48
	System	26 Sep 2020 20:32:48

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:42', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '651e21ce-a148-4ac6-96fb-90b988c6a765' User entered 'None (1)'	System	26 Sep 2020 20:32:48
	System	26 Sep 2020 20:32:48

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '651e21ce-a148-4ac6-96fb-90b988c6a765' User entered '26 Sep 2020 15:32'	System	26 Sep 2020 20:32:48
	System	26 Sep 2020 20:32:48

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 5'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:06', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '9456a85f-229c-4c70-a402-47913f3ea082' User entered 'None (1)'	System	27 Sep 2020 21:04:21
	System	27 Sep 2020 21:04:21

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:04', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '9456a85f-229c-4c70-a402-47913f3ea082'	System	27 Sep 2020 21:04:21
User entered 'No (N)'	System	27 Sep 2020 21:04:21

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '9456a85f-229c-4c70-a402-47913f3ea082'	System	27 Sep 2020 21:04:21
User entered 'No (N)'	System	27 Sep 2020 21:04:21

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '9456a85f-229c-4c70-a402-47913f3ea082'	System	27 Sep 2020 21:04:21
User entered 'None (1)'	System	27 Sep 2020 21:04:21

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:18', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '9456a85f-229c-4c70-a402-47913f3ea082' User entered '27 Sep 2020 16:04'	System	27 Sep 2020 21:04:21
	System	27 Sep 2020 21:04:21

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 6'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:40', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8c1c00c4-f005-4558-a7ad-bcdb96740afd' User entered 'None (1)'	System	28 Sep 2020 20:51:55
	System	28 Sep 2020 20:51:55

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8c1c00c4-f005-4558-a7ad-bcdb96740afd' User entered 'No (N)'	System	28 Sep 2020 20:51:55
	System	28 Sep 2020 20:51:55

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8c1c00c4-f005-4558-a7ad-bcdb96740afd' User entered 'No (N)'	System	28 Sep 2020 20:51:55
	System	28 Sep 2020 20:51:55

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:48', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8c1c00c4-f005-4558-a7ad-bcdb96740afd' User entered 'None (1)'	System	28 Sep 2020 20:51:55
	System	28 Sep 2020 20:51:55

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8c1c00c4-f005-4558-a7ad-bcdb96740afd' User entered '28 Sep 2020 15:51'	System	28 Sep 2020 20:51:55
	System	28 Sep 2020 20:51:55

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 7'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:27', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '14798f39-5f87-45b1-b324-100fe7cb058a' User entered 'None (1)'	System	30 Sep 2020 10:20:38
	System	30 Sep 2020 10:20:38

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:30', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '14798f39-5f87-45b1-b324-100fe7cb058a' User entered 'No (N)'	System	30 Sep 2020 10:20:38
	System	30 Sep 2020 10:20:38

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '14798f39-5f87-45b1-b324-100fe7cb058a' User entered 'No (N)'	System	30 Sep 2020 10:20:38
	System	30 Sep 2020 10:20:38

US3312291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '14798f39-5f87-45b1-b324-100fe7cb058a' User entered 'None (1)'	System	30 Sep 2020 10:20:38
	System	30 Sep 2020 10:20:38

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:36', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '14798f39-5f87-45b1-b324-100fe7cb058a' User entered '30 Sep 2020 05:20'	System	30 Sep 2020 10:20:38
	System	30 Sep 2020 10:20:38

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered 'None (0)'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:53', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered 'None (0)'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered 'None (0)'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T13:59:58', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered 'None (0)'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T14:00:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered 'None (0)'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T14:00:02', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered 'None (0)'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T14:00:04', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered 'No (N)'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T14:00:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'a97cb666-8c64-450c-8065-b140e71fb9eb' User entered '23 Sep 2020 14:00'	System	23 Sep 2020 19:00:10
	System	23 Sep 2020 19:00:10

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 13:43'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 16:13'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:13', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered 'None (0)'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:18', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered 'None (0)'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered 'None (0)'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:23', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered 'None (0)'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:25', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered 'None (0)'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:27', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered 'None (0)'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:30', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered 'No (N)'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-23T21:16:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '8b8b5fb7-d2c9-4d32-b2fc-726e4d2d976a' User entered '23 Sep 2020 21:16'	System	24 Sep 2020 02:16:37
	System	24 Sep 2020 02:16:37

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '23 Sep 2020 17:08'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 2'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:56', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered 'None (0)'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:57', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered 'None (0)'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:35:59', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered 'None (0)'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:36:01', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered 'None (0)'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:36:03', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered 'None (0)'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:36:05', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered 'None (0)'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:36:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered 'No (N)'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T09:36:11', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e214394f-7051-4077-9b8e-c98024b5d01b' User entered '25 Sep 2020 09:36'	System	25 Sep 2020 14:36:14
	System	25 Sep 2020 14:36:14



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 3'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:11', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered 'None (0)'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:13', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered 'None (0)'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered 'None (0)'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:21', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered 'None (0)'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:23', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered 'None (0)'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:25', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered 'None (0)'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:30', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered 'No (N)'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-25T13:22:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '37a0052e-9d44-4c5f-8777-091e19e34cd8' User entered '25 Sep 2020 13:22'	System	25 Sep 2020 18:22:34
	System	25 Sep 2020 18:22:34

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 4'	System	23 Sep 2020 18:30:16

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:47', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered 'None (0)'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered 'None (0)'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered 'None (0)'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:53', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered 'None (0)'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered 'None (0)'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:57', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered 'None (0)'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:32:59', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered 'No (N)'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-26T15:33:01', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2d740423-a164-4d69-9552-a727798c8491' User entered '26 Sep 2020 15:33'	System	26 Sep 2020 20:33:05
	System	26 Sep 2020 20:33:05

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:30:16



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 5'	System	23 Sep 2020 18:30:16

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:26', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered 'None (0)'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:28', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered 'None (0)'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:30', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered 'None (0)'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered 'None (0)'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered 'None (0)'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:36', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered 'None (0)'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered 'No (N)'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-27T16:04:53', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '933aa5b9-733c-4cee-b664-cd59f483e44d' User entered '27 Sep 2020 16:04'	System	27 Sep 2020 21:04:56
	System	27 Sep 2020 21:04:56

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 6'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered 'None (0)'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:57', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered 'None (0)'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:51:59', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered 'None (0)'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:52:01', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered 'None (0)'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:52:03', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered 'None (0)'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:52:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered 'None (0)'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:52:10', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered 'No (N)'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-28T15:52:12', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '68283be7-370d-4e70-9f93-2a1d709ca8ed' User entered '28 Sep 2020 15:52'	System	28 Sep 2020 20:52:17
	System	28 Sep 2020 20:52:17

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	23 Sep 2020 18:30:16
User entered 'Day 7'	System	23 Sep 2020 18:30:16

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:41', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered 'None (0)'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01



US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered 'None (0)'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:46', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered 'None (0)'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:48', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered 'None (0)'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered 'None (0)'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered 'None (0)'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:54', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered 'No (N)'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01

**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-09-30T05:20:56', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c50ec8d3-4f5a-4d8c-b327-905d4e02ed1d' User entered '30 Sep 2020 05:20'	System	30 Sep 2020 10:21:01
	System	30 Sep 2020 10:21:01

US3312291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:30:16



**US3312291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:30:16

**US3312291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:02

**US3312291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '01 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:02

**US3312291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:02

US3312291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:02

**US3312291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:06

**US3312291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'I'	System	08 Oct 2020 23:20:06

**US3312291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:24



**US3312291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:24

**US3312291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:24

US3312291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:24

US3312291

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 23:20:28

**US3312291**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'I'	System	08 Oct 2020 23:20:28

**US3312291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:25

**US3312291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:25

**US3312291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:25



US3312291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:25

**US3312291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:30

**US3312291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'I'	System	28 Oct 2020 15:02:30

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:06

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:06

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:06

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'VISIT3'	System	28 Oct 2020 15:03:06

US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26



US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '09:47'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered '21 Oct 2020 09:47'	System	28 Oct 2020 15:03:26

US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '67'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'bpm'	System	28 Oct 2020 15:03:26



US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '14'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'breaths/min'	System	28 Oct 2020 15:03:26

US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '118'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'mmHg'	System	28 Oct 2020 15:03:26

US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '62'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:26

US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'mmHg'	System	28 Oct 2020 15:03:26

US3312291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50



**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:34

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:34

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:45

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:45

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered '09:56'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:45

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered '21 Oct 2020 09:56'	System	28 Oct 2020 15:03:45

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:32:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:53

**US3312291**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'I'	System	28 Oct 2020 15:03:53



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 64'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-10-28T09:17:27', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '1ebdafa7-0b80-49b9-be00-cb22c0885533'	System	28 Oct 2020 14:17:46
User entered 'No (N)'	System	28 Oct 2020 14:17:46

US3312291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-10-28T09:17:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '1ebdafa7-0b80-49b9-be00-cb22c0885533'	System	28 Oct 2020 14:17:46
User entered 'No (N)'	System	28 Oct 2020 14:17:46

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-10-28T09:17:43', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '1ebdafa7-0b80-49b9-be00-cb22c0885533' User entered '28 Oct 2020 09:17:43'	System	28 Oct 2020 14:17:46
	System	28 Oct 2020 14:17:46

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 71'	System	26 Aug 2020 16:07:59

US3312291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-05T14:36:54', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'b81a21a2-7204-49b4-b338-cbe45a3f08a3'	System	05 Nov 2020 20:37:24
User entered 'No (N)'	System	05 Nov 2020 20:37:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-05T14:37:11', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'b81a21a2-7204-49b4-b338-cbe45a3f08a3'	System	05 Nov 2020 20:37:24
User entered 'No (N)'	System	05 Nov 2020 20:37:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-05T14:37:17', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'b81a21a2-7204-49b4-b338-cbe45a3f08a3' User entered '05 Nov 2020 14:37:17'	System	05 Nov 2020 20:37:24
	System	05 Nov 2020 20:37:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered 'Day 78'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-11T16:54:12', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'b5eb78a5-2766-4224-b83d-59888341dfe7' User entered 'No (N)'	System	11 Nov 2020 22:54:23
	System	11 Nov 2020 22:54:23

US3312291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-11T16:54:17', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'b5eb78a5-2766-4224-b83d-59888341dfe7'	System	11 Nov 2020 22:54:23
User entered 'No (N)'	System	11 Nov 2020 22:54:23

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-11T16:54:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'b5eb78a5-2766-4224-b83d-59888341dfe7' User entered '11 Nov 2020 16:54:20'	System	11 Nov 2020 22:54:23
	System	11 Nov 2020 22:54:23



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:28:55
Data entry locked.	System	26 Aug 2020 16:07:59
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 16:07:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-23T07:26:45', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c5af0b99-19b1-423b-8413-25b39fa3c8f7'	System	23 Nov 2020 13:26:59
User entered 'No (N)'	System	23 Nov 2020 13:26:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-23T07:26:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c5af0b99-19b1-423b-8413-25b39fa3c8f7'	System	23 Nov 2020 13:26:59
User entered 'No (N)'	System	23 Nov 2020 13:26:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-23T07:26:56', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c5af0b99-19b1-423b-8413-25b39fa3c8f7'	System	23 Nov 2020 13:26:59
User entered '23 Nov 2020 07:26:56'	System	23 Nov 2020 13:26:59

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-27T15:55:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6a9ab119-642e-4790-bd21-83bfc54680dc' User entered 'No (N)'	System	27 Nov 2020 22:56:04
	System	27 Nov 2020 22:56:04

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-27T15:55:58', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6a9ab119-642e-4790-bd21-83bfc54680dc' User entered 'No (N)'	System	27 Nov 2020 22:56:04

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-11-27T15:56:01', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6a9ab119-642e-4790-bd21-83bfc54680dc' User entered '27 Nov 2020 15:56:01'	System	27 Nov 2020 22:56:04
	System	27 Nov 2020 22:56:04

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-06T12:27:28', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '926bfacd-12a8-4ae9-8f83-945333898f3e' User entered 'No (N)'	System	06 Dec 2020 18:27:37
	System	06 Dec 2020 18:27:37



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-06T12:27:33', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '926bfacd-12a8-4ae9-8f83-945333898f3e' User entered 'No (N)'	System	06 Dec 2020 18:27:37
	System	06 Dec 2020 18:27:37

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-06T12:27:35', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '926bfacd-12a8-4ae9-8f83-945333898f3e' User entered '06 Dec 2020 12:27:35'	System	06 Dec 2020 18:27:37
	System	06 Dec 2020 18:27:37

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-13T12:00:31', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6e572746-8153-4183-8d1b-3fe21a4cd865'	System	13 Dec 2020 18:00:42
User entered 'No (N)'	System	13 Dec 2020 18:00:42

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-13T12:00:35', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6e572746-8153-4183-8d1b-3fe21a4cd865'	System	13 Dec 2020 18:00:42
User entered 'No (N)'	System	13 Dec 2020 18:00:42

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-13T12:00:38', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '6e572746-8153-4183-8d1b-3fe21a4cd865' User entered '13 Dec 2020 12:00:38'	System	13 Dec 2020 18:00:42
	System	13 Dec 2020 18:00:42



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-18T09:21:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '3666617d-4e31-4829-bfa9-e02538bd6294' User entered 'No (N)'	System	18 Dec 2020 15:21:49
	System	18 Dec 2020 15:21:49

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-18T09:21:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '3666617d-4e31-4829-bfa9-e02538bd6294' User entered 'No (N)'	System	18 Dec 2020 15:21:49

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-18T09:21:47', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '3666617d-4e31-4829-bfa9-e02538bd6294' User entered '18 Dec 2020 09:21:47'	System	18 Dec 2020 15:21:49
	System	18 Dec 2020 15:21:49

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-28T14:54:27', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd00c2a87-0891-4715-920b-d5f436e489db' User entered 'No (N)'	System	28 Dec 2020 20:54:35
	System	28 Dec 2020 20:54:35

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-28T14:54:29', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd00c2a87-0891-4715-920b-d5f436e489db' User entered 'No (N)'	System	28 Dec 2020 20:54:35

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2020-12-28T14:54:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'd00c2a87-0891-4715-920b-d5f436e489db' User entered '28 Dec 2020 14:54:32'	System	28 Dec 2020 20:54:35
	System	28 Dec 2020 20:54:35

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-03T12:00:29', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '77642bb4-2402-4379-b402-95ab4d48f3d0'	System	03 Jan 2021 18:00:41
User entered 'No (N)'	System	03 Jan 2021 18:00:41



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-03T12:00:32', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '77642bb4-2402-4379-b402-95ab4d48f3d0'	System	03 Jan 2021 18:00:41
User entered 'No (N)'	System	03 Jan 2021 18:00:41

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-03T12:00:36', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '77642bb4-2402-4379-b402-95ab4d48f3d0' User entered '03 Jan 2021 12:00:36'	System	03 Jan 2021 18:00:41
	System	03 Jan 2021 18:00:41

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-08T23:34:30', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f2fb1c80-43ed-4fd5-a5ec-a8de504478b7' User entered 'No (N)'	System	09 Jan 2021 05:36:46
	System	09 Jan 2021 05:36:46

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-08T23:34:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f2fb1c80-43ed-4fd5-a5ec-a8de504478b7'	System	09 Jan 2021 05:36:46
User entered 'No (N)'	System	09 Jan 2021 05:36:46

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-08T23:34:40', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f2fb1c80-43ed-4fd5-a5ec-a8de504478b7' User entered '08 Jan 2021 23:34:40'	System	09 Jan 2021 05:36:46



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-15T08:07:19', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e79a1b90-21de-4ce0-bfbb-15df4e892a2f' User entered 'No (N)'	System	15 Jan 2021 14:07:32

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-15T08:07:25', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e79a1b90-21de-4ce0-bfbb-15df4e892a2f' User entered 'No (N)'	System	15 Jan 2021 14:07:32

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-15T08:07:28', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'e79a1b90-21de-4ce0-bfbb-15df4e892a2f' User entered '15 Jan 2021 08:07:28'	System	15 Jan 2021 14:07:32

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-24T12:02:20', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dbb31a0a-5577-463c-8120-117449dfd716'	System	24 Jan 2021 18:03:56
User entered 'No (N)'	System	24 Jan 2021 18:03:56

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-24T12:02:23', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dbb31a0a-5577-463c-8120-117449dfd716'	System	24 Jan 2021 18:03:56
User entered 'No (N)'	System	24 Jan 2021 18:03:56

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-24T12:02:26', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'dbb31a0a-5577-463c-8120-117449dfd716'	System	24 Jan 2021 18:03:56
User entered '24 Jan 2021 12:02:26'	System	24 Jan 2021 18:03:56

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-31T12:00:14', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '796be7ae-66a6-4e7f-9680-f17bcb2e4052'	System	31 Jan 2021 18:00:36
User entered 'No (N)'	System	31 Jan 2021 18:00:36



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-31T12:00:18', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '796be7ae-66a6-4e7f-9680-f17bcb2e4052'	System	31 Jan 2021 18:00:36
User entered 'No (N)'	System	31 Jan 2021 18:00:36

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-01-31T12:00:21', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '796be7ae-66a6-4e7f-9680-f17bcb2e4052' User entered '31 Jan 2021 12:00:21'	System	31 Jan 2021 18:00:36
	System	31 Jan 2021 18:00:36

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-07T12:00:38', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '725ce823-5ae7-4997-a879-064782c0eebd' User entered 'No (N)'	System	07 Feb 2021 18:01:11
	System	07 Feb 2021 18:01:11

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-07T12:00:40', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '725ce823-5ae7-4997-a879-064782c0eebd' User entered 'No (N)'	System	07 Feb 2021 18:01:11

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-07T12:00:44', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '725ce823-5ae7-4997-a879-064782c0eebd' User entered '07 Feb 2021 12:00:44'	System	07 Feb 2021 18:01:11
	System	07 Feb 2021 18:01:11



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-12T09:18:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '42bee9cd-505d-4e60-9f9d-bf3a223c0f44'	System	12 Feb 2021 15:18:24
User entered 'No (N)'	System	12 Feb 2021 15:18:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-12T09:18:19', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '42bee9cd-505d-4e60-9f9d-bf3a223c0f44'	System	12 Feb 2021 15:18:24
User entered 'No (N)'	System	12 Feb 2021 15:18:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-12T09:18:22', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '42bee9cd-505d-4e60-9f9d-bf3a223c0f44'	System	12 Feb 2021 15:18:24
User entered '12 Feb 2021 09:18:22'	System	12 Feb 2021 15:18:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-19T11:02:48', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '44736e93-7286-4cd5-93b8-7ece2616dcce' User entered 'No (N)'	System	19 Feb 2021 17:10:25
	System	19 Feb 2021 17:10:25

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-19T11:02:51', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '44736e93-7286-4cd5-93b8-7ece2616dcce' User entered 'No (N)'	System	19 Feb 2021 17:10:25

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-19T11:02:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '44736e93-7286-4cd5-93b8-7ece2616dcce' User entered '19 Feb 2021 11:02:55'	System	19 Feb 2021 17:10:25
	System	19 Feb 2021 17:10:25

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-28T09:44:54', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '427ce493-9402-4276-926f-ac6e79a9e863' User entered 'No (N)'	System	28 Feb 2021 15:45:06
	System	28 Feb 2021 15:45:06



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-28T09:44:55', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '427ce493-9402-4276-926f-ac6e79a9e863' User entered 'No (N)'	System	28 Feb 2021 15:45:06
	System	28 Feb 2021 15:45:06

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-02-28T09:45:03', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '427ce493-9402-4276-926f-ac6e79a9e863' User entered '28 Feb 2021 09:45:03'	System	28 Feb 2021 15:45:06
	System	28 Feb 2021 15:45:06

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-08T14:02:41', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bd31701a-ce09-463f-8a29-06313b477196'	System	08 Mar 2021 20:03:39
User entered 'No (N)'	System	08 Mar 2021 20:03:39

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-08T14:02:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bd31701a-ce09-463f-8a29-06313b477196'	System	08 Mar 2021 20:03:39
User entered 'No (N)'	System	08 Mar 2021 20:03:39

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-08T14:02:52', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'bd31701a-ce09-463f-8a29-06313b477196' User entered '08 Mar 2021 14:02:52'	System	08 Mar 2021 20:03:39



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-14T15:15:03', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2ce2c471-723a-42c9-a542-cf4960aaf9e0' User entered 'No (N)'	System	14 Mar 2021 20:15:18
	System	14 Mar 2021 20:15:18

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-14T15:15:09', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2ce2c471-723a-42c9-a542-cf4960aaf9e0'	System	14 Mar 2021 20:15:18
User entered 'No (N)'	System	14 Mar 2021 20:15:18

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-14T15:15:12', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2ce2c471-723a-42c9-a542-cf4960aaf9e0' User entered '14 Mar 2021 15:15:12'	System	14 Mar 2021 20:15:18
	System	14 Mar 2021 20:15:18

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-21T12:30:02', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c0017a5a-9d39-4c8e-8304-6e962054282d' User entered 'No (N)'	System	21 Mar 2021 17:30:12

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-21T12:30:06', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c0017a5a-9d39-4c8e-8304-6e962054282d' User entered 'No (N)'	System	21 Mar 2021 17:30:12

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-21T12:30:08', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'c0017a5a-9d39-4c8e-8304-6e962054282d' User entered '21 Mar 2021 12:30:08'	System	21 Mar 2021 17:30:12

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-26T11:14:35', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '220a51fb-e586-4225-acbd-ad4bdeb2cc3c' User entered 'No (N)'	System	26 Mar 2021 16:21:35
	System	26 Mar 2021 16:21:35



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-26T11:14:37', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '220a51fb-e586-4225-acbd-ad4bdeb2cc3c' User entered 'No (N)'	System	26 Mar 2021 16:21:35
	System	26 Mar 2021 16:21:35

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-26T11:14:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '220a51fb-e586-4225-acbd-ad4bdeb2cc3c' User entered '26 Mar 2021 11:14:39'	System	26 Mar 2021 16:21:35
	System	26 Mar 2021 16:21:35

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-04T12:19:09', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '0457748d-0a06-4f66-81a1-f6a4a0381f30' User entered 'No (N)'	System	04 Apr 2021 17:19:26
	System	04 Apr 2021 17:19:26

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-04T12:19:13', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '0457748d-0a06-4f66-81a1-f6a4a0381f30' User entered 'No (N)'	System	04 Apr 2021 17:19:26

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-04T12:19:16', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '0457748d-0a06-4f66-81a1-f6a4a0381f30' User entered '04 Apr 2021 12:19:16'	System	04 Apr 2021 17:19:26
	System	04 Apr 2021 17:19:26



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-12T14:57:33', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1b91bc3-6ffa-4f34-886a-eab55ed4b972'	System	12 Apr 2021 19:57:42
User entered 'No (N)'	System	12 Apr 2021 19:57:42

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-12T14:57:36', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1b91bc3-6ffa-4f34-886a-eab55ed4b972'	System	12 Apr 2021 19:57:42
User entered 'No (N)'	System	12 Apr 2021 19:57:42

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-12T14:57:39', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'f1b91bc3-6ffa-4f34-886a-eab55ed4b972'	System	12 Apr 2021 19:57:42
User entered '12 Apr 2021 14:57:39'	System	12 Apr 2021 19:57:42

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-17T20:35:27-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '93c73820-8946-45b7-8449-1fbeeae6e096'	System	18 Apr 2021 01:35:41
User entered 'No (N)'	System	18 Apr 2021 01:35:41

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-17T20:35:30-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '93c73820-8946-45b7-8449-1fbeeae6e096'	System	18 Apr 2021 01:35:41
User entered 'No (N)'	System	18 Apr 2021 01:35:41

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-17T20:35:35-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '93c73820-8946-45b7-8449-1fbeeae6e096'	System	18 Apr 2021 01:35:41
User entered '17 Apr 2021 20:35:35'	System	18 Apr 2021 01:35:41

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-23T13:59:31-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2bf95413-c96b-4beb-8e10-b4cef3470552'	System	23 Apr 2021 18:59:40
User entered 'No (N)'	System	23 Apr 2021 18:59:40



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-23T13:59:34-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2bf95413-c96b-4beb-8e10-b4cef3470552'	System	23 Apr 2021 18:59:40
User entered 'No (N)'	System	23 Apr 2021 18:59:40

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-23T13:59:37-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '2bf95413-c96b-4beb-8e10-b4cef3470552'	System	23 Apr 2021 18:59:40
User entered '23 Apr 2021 13:59:37'	System	23 Apr 2021 18:59:40

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-30T06:49:08-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '444269bf-dd4d-4510-affd-b9d09de59c96'	System	30 Apr 2021 11:49:29
User entered 'No (N)'	System	30 Apr 2021 11:49:29

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

Have you been exposed to someone with 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 (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-30T06:49:12-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '444269bf-dd4d-4510-affd-b9d09de59c96'	System	30 Apr 2021 11:49:29
User entered 'No (N)'	System	30 Apr 2021 11:49:29

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-04-30T06:49:25-05:00', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: '444269bf-dd4d-4510-affd-b9d09de59c96'	System	30 Apr 2021 11:49:29
User entered '30 Apr 2021 06:49:25'	System	30 Apr 2021 11:49:29



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:05:24



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

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**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:05:24



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:05:24

**US3312291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:05:24



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:05:24



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:05:24



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:05:24



**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:05:24



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:05:24

**US3312291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:05:24
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:05:24

US3312291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:58:08

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 16:32:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-01T07:28:34', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'ff06b088-59e8-42a6-bba3-9b10137b9d77'	System	01 Mar 2021 13:28:51
User entered 'No (N)'	System	01 Mar 2021 13:28:51

**US3312291**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:32:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8E312D57-BE07-4BFC-B2E5-7CCA7CE48131)', Time: '2021-03-01T07:28:49', User OID: 'PatientReportedOutcome (US3312291)', ODM File OID: 'ff06b088-59e8-42a6-bba3-9b10137b9d77'	System	01 Mar 2021 13:28:51
User entered '01 Mar 2021 07:28:49'	System	01 Mar 2021 13:28:51

**US3312291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:18:34

**US3312291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:18:34



**US3312291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:18:34

**US3312291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:18:34

**US3312291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:18:39

**US3312291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:50
User entered 'I'	System	19 Nov 2020 15:18:39

**US3312291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:27:13

**US3312291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:27:13

**US3312291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:27:13

**US3312291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:27:13



**US3312291**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:27:03

**US3312291**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered 'I'	System	22 Dec 2020 21:27:03

**US3312291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:53:33

**US3312291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:53:33

**US3312291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:53:33

US3312291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:53:33

**US3312291**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:53:37

**US3312291**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered 'I'	System	25 Jan 2021 16:53:37



**US3312291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:43:15

**US3312291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:43:15

**US3312291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:43:15

**US3312291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:43:15

**US3312291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:43:17

**US3312291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered '1'	System	18 Feb 2021 15:43:17

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:17:58

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:17:58



**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[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 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:17:58

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered 'VISIT4'	System	29 Mar 2021 15:17:58

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered empty.	System	29 Mar 2021 15:18:03

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03



**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered empty.	System	29 Mar 2021 15:18:03

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered empty.	System	29 Mar 2021 15:18:03

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered empty.	System	29 Mar 2021 15:18:03

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:03



**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered empty.	System	29 Mar 2021 15:18:03

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32

US3312291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:05

US3312291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:05

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:20

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:20

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:30'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:20



**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered '29 Mar 2021 09:30'	System	29 Mar 2021 15:18:20

US3312291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:23

**US3312291**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:15:32
User entered 'I'	System	29 Mar 2021 15:18:23

**US3312291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:43:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:33:48

**US3312291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:43:24
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:33:48

**US3312291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:43:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:33:48

**US3312291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:43:24
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:33:48

**US3312291**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:43:24
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 13:33:52



**US3312291**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 13:33:52

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:58:08

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample been collected under COVID Diagnostic Test then update the details under appropriate visit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:00:40
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample been collected under COVID Diagnostic Test then update the details under appropriate visit. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:39:04
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample been collected under COVID Diagnostic Test then update the details under appropriate visit. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:40:47
User entered '02 Nov 2020'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:33:17

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:58:08**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:31'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:33:17

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:58:08

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:29
User entered '02 Nov 2020 09:31'	System	11 Nov 2020 16:33:17

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:58:08**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Safety Call (Safety Call)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:33:17

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:58:08**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:33:17

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '30 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:33:52
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User entered '%'	System	18 Dec 2020 17:33:52
User entered empty.	System	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:33:52
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:33
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:33
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33



US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:33
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:33
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:33
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:33

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '31 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:33:52
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53



US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User entered '%'	System	18 Dec 2020 17:33:52
User entered empty.	System	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:33:52
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:53
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:53
	(b) (4)	



US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:53
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53



US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:38:53
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:38:53

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:33:52
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User entered '%'	System	18 Dec 2020 17:33:52
User entered empty.	System	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:33:52
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:39:12
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:39:12
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12



US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:12



US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User closed query 'per CDM: please confirm symptom day for 02 Nov 2020, as 31 Oct 2020 also noted as day 2' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 10:00:50
Query 'per CDM: please confirm symptom day for 02 Nov 2020, as 31 Oct 2020 also noted as day 2' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Mar 2021 22:53:31
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Mar 2021 22:53:24
User opened query 'per CDM: please confirm symptom day for 02 Nov 2020, as 31 Oct 2020 also noted as day 2' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 07:48:19
User entered 'Day 2 (Day 2)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '02 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '100'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:08**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User entered '%'	System	11 Nov 2020 16:39:43

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '97.9' F	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43



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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:39:43
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:39:43
	(b) (4)	



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**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:39:43

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '03 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User entered '%'	System	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '97.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:40:25
	(b) (4)	



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:40:25
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:40:25
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:40:25

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '04 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '99'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03



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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User entered '%'	System	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '97.9' F	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:41:03
	(b) (4)	

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**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03



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Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:41:03
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:41:03
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:41:03
	(b) (4)	



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Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:41:03

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '05 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '99'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User entered '%'	System	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '96.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:42:40
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:42:40
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40



US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:42:40
	(b) (4)	

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:37
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:42:40



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '02 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:42

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:08**

[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 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:42

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:08**

[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 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:42

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:58:08

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 18:38:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 18:38:49
User entered '02 Nov 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Nov 2020 18:38:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 18:38:42
User entered empty.	System	23 Nov 2020 18:38:42
	Karol Moore (b) (4)	23 Nov 2020 18:38:42
	(b) (4)	

**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:08**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4)	23 Nov 2020 18:38:42

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:58:08

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:42

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:58:08

[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 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:42

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:58:08

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:42



**US3312291**

**Folder: Covid-19 Assessment 02 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:08**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:42

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:58:08

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:42
User entered '0'	System	23 Nov 2020 18:38:42

US3312291

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:58:08

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:46
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:38:54

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:49:38

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered '04 Nov 2020'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

US3312291

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:58:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:49:38

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	



**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

US3312291

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:58:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:49:38

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

US3312291

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:58:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:49:38

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:49:38



**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:49:38

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:49:38

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	

**US3312291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:49:38
	(b) (4)	



**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:46:49

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '02 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:46:49

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[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 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:46:49

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered 'SICKD1'	System	11 Nov 2020 16:46:49

US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '02 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '10:40'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered '02 Nov 2020 10:40'	System	11 Nov 2020 16:47:20



US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '64' in	(b) (4)	11 Nov 2020 16:47:20
DataPoint set to visible.	Karol Moore (b) (4)	11 Nov 2020 16:46:49
	(b) (4)	
	System	

US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '184.9' lb	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:47:20
DataPoint set to visible.	(b) (4) System	11 Nov 2020 16:46:49

US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '97.9' F	(b) (4)	11 Nov 2020 16:47:20
	Karol Moore (b) (4)	
	(b) (4)	

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '74'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered 'bpm'	System	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20



US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered 'breaths/min'	System	11 Nov 2020 16:47:20

US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '161'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered 'mmHg'	System	11 Nov 2020 16:47:20

US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:42:14
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS, AE ADDED' (Site from System).	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:34
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		11 Nov 2020 16:47:20
User entered '109'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:20

US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered 'mmHg'	System	11 Nov 2020 16:47:20

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34

US3312291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34

**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:42



**US3312291**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '02 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:42

US3312291

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:58:08

[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 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	11 Nov 2020 16:47:56

US3312291

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:58:08

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '02 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 16:47:56

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	11 Nov 2020 16:48:24
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:24
	(b) (4)	

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:08

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:24
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	11 Nov 2020 16:48:24

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	



US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:28

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:28



US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:28

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:28

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:28
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:28

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	11 Nov 2020 16:48:31
	(b) (4)	

US3312291

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:31
	(b) (4)	



US3312291

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 16:58:08**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	11 Nov 2020 16:48:34
	(b) (4)	

**US3312291**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 16:58:08**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	11 Nov 2020 16:48:34
	(b) (4)	

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:01

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:01

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[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 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:01

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 14:38:01

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[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 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:59:32



**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
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 13:59:32

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:19

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:58:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '1'	System	03 Feb 2021 14:38:19



**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'I'	System	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered empty.	System	03 Feb 2021 14:39:55
DataPoint set to visible.	System	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered empty.	System	03 Feb 2021 14:39:55
DataPoint set to visible.	System	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Feb 2021 14:39:55



**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:26'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Feb 2021 09:26'	System	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '68'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55



**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'bpm'	System	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '14'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'breaths/min'	System	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '127'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	03 Feb 2021 14:39:55

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '67'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55



**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered empty.	System	03 Feb 2021 14:39:55
DataPoint set to visible.	System	03 Feb 2021 14:38:19

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '10:54'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Feb 2021 10:54'	System	03 Feb 2021 14:39:55

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55



US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '61'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'bpm'	System	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '14'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'breaths/min'	System	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '130'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	03 Feb 2021 14:39:55



**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '67'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	03 Feb 2021 14:39:55

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:04

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:04

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:20

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:20

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

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)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:20

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mRNA-1273'	System	03 Feb 2021 14:40:20
DataPoint set to visible.	System	03 Feb 2021 14:38:19



US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:20

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '10:23'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:20

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Feb 2021 10:23'	System	03 Feb 2021 14:40:20

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:40:20

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'ONCE'	System	03 Feb 2021 14:40:20

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 14:40:20

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:27

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:27



**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:16'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:27

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Feb 2021 09:16'	System	03 Feb 2021 14:38:27

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:35

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:35

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:08**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:15'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:35

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:08**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Feb 2021 09:15'	System	03 Feb 2021 14:38:35

US3312291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:38:38

**US3312291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '1'	System	03 Feb 2021 14:38:38



**US3312291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:44:15

**US3312291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:44:15

**US3312291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:44:15

**US3312291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:44:15

**US3312291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:44:18

**US3312291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'I'	System	18 Feb 2021 15:44:18

**US3312291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '1'	System	18 Feb 2021 15:44:18
DataPoint set to visible.	System	18 Feb 2021 15:44:18

**US3312291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:20:44



**US3312291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:20:44

**US3312291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[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 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:20:44

**US3312291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'OLD29'	System	02 Mar 2021 20:20:44

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:00'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Mar 2021 09:00'	System	02 Mar 2021 20:23:16



US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '73'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'bpm'	System	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '12'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'breaths/min'	System	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '140'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16



**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '78'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '10:15'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Mar 2021 10:15'	System	02 Mar 2021 20:23:16



US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '64'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'bpm'	System	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'breaths/min'	System	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '133'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16



US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '73'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:16

**US3312291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mmHg'	System	02 Mar 2021 20:23:16

US3312291

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:48

**US3312291**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:48

**US3312291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:12

**US3312291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:12

US3312291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

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)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:12



**US3312291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'mRNA-1273'	System	02 Mar 2021 20:24:12
DataPoint set to visible.	System	18 Feb 2021 15:44:18

US3312291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:12

**US3312291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:44'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:12

**US3312291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered '01 Mar 2021 09:44'	System	02 Mar 2021 20:24:12

US3312291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:12

US3312291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'ONCE'	System	02 Mar 2021 20:24:12

US3312291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 20:24:12

**US3312291**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:20



**US3312291**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'I'	System	02 Mar 2021 20:24:20

**US3312291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:13:28

**US3312291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:13:28

**US3312291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:13:28

**US3312291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:13:28

**US3312291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:13:33

**US3312291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:53:40
User entered 'I'	System	16 Mar 2021 18:13:33

**US3312291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:18:33



**US3312291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:33

**US3312291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:33

**US3312291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:08**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 15:18:33

US3312291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40



**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 15:18:40

US3312291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 15:18:40

US3312291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 15:18:40



**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 15:18:40

**US3312291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:18:43

**US3312291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:18:43

**US3312291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:50

US3312291

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:50

**US3312291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '09:30'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:18:50

**US3312291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 09:30'	System	29 Mar 2021 15:18:50



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 16:58:08**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:54:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:56

US3312291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
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)	11 Nov 2020 17:14:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 17:14:34
	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 17:13:24
User entered 'SORE THROAT'	(b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:12:52



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

US3312291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 17:12:52

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Per DM CLR: Please review if this symptom should be combined with AE #2, as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:11:22
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure systolic increased, LLT: Blood pressure systolic increased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:09:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:09:16
Data point term sent to Coder	System	08 Apr 2021 17:28:59
Query 'Per DM CLR: Please review if this symptom should be combined with AE #2, as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate. ' answered with 'combined' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:28:42
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 17:28:35
User entered 'ELEVATED DIASTOLIC and systolic BLOOD PRESSURE' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:28:35
User opened query 'Per DM CLR: Please review if this symptom should be combined with AE #2, as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:07:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 ELEVATED SYSTOLIC BLOOD PRESSURE, as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:41:40
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure diastolic increased, LLT: Diastolic blood pressure increased - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 18:28:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Mar 2021 18:28:47
Data point term sent to Coder	System	17 Mar 2021 18:27:23
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 18:26:34
User entered 'ELEVATED DIASTOLIC BLOOD PRESSURE' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 18:26:34
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 ELEVATED SYSTOLIC BLOOD PRESSURE, as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate.'	(b) (4), (b) (6)	17 Mar 2021 18:26:23
answered with 'entered per protocol-separate on tox table (per protocol)' (Site from DM).		
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 ELEVATED SYSTOLIC BLOOD PRESSURE, as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:53:48
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure diastolic increased, LLT: Blood pressure diastolic increased - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 00:09:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) System	14 Nov 2020 00:09:35
User entered 'elevated diastolic blood pressure causes'	(b) (4), (b) (6)	13 Nov 2020 19:14:41 13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User entered empty.	System	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:49:32
User entered '12 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User entered empty.	System	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	17 Mar 2021 18:25:55
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32



US3312291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:23:30
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#4) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:10:33
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#4) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 16:47:10
User entered '0' reason for change: Data Entry Error	Karol Moore (b) (4)	17 Dec 2020 16:47:05
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#4) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:18:49
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 19:14:32

US3312291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:42:13
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:23:37
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 18:23:30
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:54:35
User entered '1' reason for change: Data Entry Error	Karol Moore (b) (4)	17 Dec 2020 16:47:05
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User entered '0'	System	13 Nov 2020 19:14:32

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13
User entered 'I'	System	13 Nov 2020 19:14:32



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:13

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17

US3312291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
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)	13 Nov 2020 19:16:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:16:49
Data point term sent to Coder	System	13 Nov 2020 19:15:43
User entered 'COUGH'	(b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User entered empty.	System	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User entered empty.	System	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User entered '0'	System	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17
User entered 'I'	System	13 Nov 2020 19:15:42

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29

US3312291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
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)	13 Nov 2020 19:18:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:18:49
Data point term sent to Coder	System	13 Nov 2020 19:17:45
User entered 'HEADACHE'	(b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User entered empty.	System	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User entered empty.	System	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User entered '0'	System	13 Nov 2020 19:17:17

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29
User entered '1'	System	13 Nov 2020 19:17:17



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Per DM CLR - RQ: Site's response noted. However, AE #2 and 3 is still HYPERTENSION by definition. Please reconcile and update AE entries so there is no overlap or duplicate data. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:38:43
Query 'Per DM CLR - RQ: Site's response noted. However, AE #2 and 3 is still HYPERTENSION by definition. Please reconcile and update AE entries so there is no overlap or duplicate data. ' answered with 'updated AE dates 1 and 2' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:50:04
User opened query 'Per DM CLR - RQ: Site's response noted. However, AE #2 and 3 is still HYPERTENSION by definition. Please reconcile and update AE entries so there is no overlap or duplicate data. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:35:47
User closed query 'Per DM CLR: Please note this AE overlaps with AE#1 & 2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 15:38:46
Query 'Per DM CLR: Please note this AE overlaps with AE#1 & 2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'CORRECT AS ENTERED. AE#1 & AE#2 WERE EPISODES, WHERE AE#6 IS A DIAGNOSIS' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 16:48:41
User opened query 'Per DM CLR: Please note this AE overlaps with AE#1 & 2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:19:03
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 19:19:49

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Nov 2020 19:19:49
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 19:18:48
User entered 'HYPERTENSION'	(b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:57:58
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:18:35

US3312291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	21 Dec 2020 20:57:58
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	21 Dec 2020 20:57:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 20:57:38
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

US3312291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:08

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:38:20
Query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:50:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:50:22
User opened query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 08:55:49
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:57:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Nov 2020 19:18:35



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 19:18:35

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 14:42:17
Un-reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 14:42:13
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 17:45:33
User entered	System	22 Dec 2020 17:45:29
'USA-US300-2020-mRNA-1273-P301000025'		
User entered 'New'	(b) (4), (b) (6)	22 Dec 2020 17:45:29

US3312291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:33:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:33:46
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 20:41:19
User entered 'cholecystitis'	(b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 20:40:28



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

US3312291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'PV Query: Per narrative, the subject was hospitalized from 28Nov2020-29Nov2020. Hospitalization and discharge date of 27Nov2020-28Nov2020 was entered for the event. Please reconcile.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:53:01
Query 'PV Query: Per narrative, the subject was hospitalized from 28Nov2020-29Nov2020. Hospitalization and discharge date of 27Nov2020-28Nov2020 was entered for the event. Please reconcile.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:29:07
User entered '28 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 18:27:48
User opened query 'PV Query: Per narrative, the subject was hospitalized from 28Nov2020-29Nov2020. Hospitalization and discharge date of 27Nov2020-28Nov2020 was entered for the event. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:13:30
User entered '27 Nov 2020'	(b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:27:48
User entered '28 Nov 2020'	(b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28



US3312291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed 8-11 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:10:46
Query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed 8-11 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:29:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:29:26
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed 8-11 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:45:36
User closed query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication 'CHOLECYSTITIS' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:39:12
Query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication 'CHOLECYSTITIS' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' answered with 'Con procedure updated to include cholecystectomy, no CM at this time. medical records penidng' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:46:50
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:46:39

US3312291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication '  CHOLECYSTITIS' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' (Site from DM). User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 08:58:06
	(b) (4), (b) (6) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:58:55

US3312291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS THE SOURCE FOR THIS SAE REPORT.64 YR OLD WOMAN WITH H/O HTN, GERD AND INSOMNIA WHO AT HER MONTHLY PHONE CALL ON 12/21/2020 REPORTED LAPAROSCOPIC CHOLECYSTECTOMY (11/28/2020) RELATED TO CHOLECYSTITIS. REPORTS THAT WHILE IN ARIZONA OVER THANKSGIVING,BEGAN HAVING RIGHT-SIDED ABDOMINAL PAIN ON 11/27/2020.WENT TO THE ER AROUND 12:30 ON 11/28/2020 WHERE SHE WAS DIAGNOSED WITH CHOLECYSTITIS AND UNDERWENT LAPAROSCOPIC CHOLECYSTECTOMY THAT SAME DAY. WAS HOSPITALIZED POST-OPERATIVELY, OVERNIGHT, AND DISCHARGED THE NEXT THE NEXT MORNING ON 11/29/2020. SHE DENIES ANY COMPLICATIONS OR NEW MEDICATIONS RELATED TO SAE, INCLUDING NOT TAKING MEDICATION FOR PAIN CONTROL.HAS SINCE FOLLOWED UP WITH HER PCP ON 12/17/2020 WITH NO FURTHER CONCERNS.AT TIME OF CONTACT, SHE HAS RETURNED TO HER BASELINE HEALTH AND ACTIVITY.THIS IS AN SAE, HOSPITALIZATION (11/28/2020 TO 11/29/2020), NOT RELATED TO IP. MEDICAL RECORDS WILL BE REQUESTED UPON RECEIPT OF SIGNED MEDICAL RECORDS RELEASE FROM SUBJECT.WILL CLOSE SAE AFTER REVIEW OF MEDICAL RECORDS. Update 30Mar2021:Rt-sided abd pain on night of 27Nov2020. Went to ER around 12:40 on 28Nov2020 c/o abd pain 9/10 , nausea/vomiting, not responsive to Aleve, Alka-Seltzer, Pepto Bismol. T98.2 HR76, RR16, SpO298, O2 RA, BP163/95. Rec'd Ketorolac 30 mg IM x1. White count WNL at 10, LFTs WNL, CXR normal, US showed gallstone impacted in infundibulum with gallbladder wall thickening/edema. CBD nml:4 mm. On exam, tender RUQ, positive Murphy sign. To OR for laparoscopic cholecystectomy with intraoperative cholangiogram.	Heather Barker (b) (4)	30 Mar 2021 19:35:53

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

[Narrative](#)

Audit	User	Time (GMT)
Tolerated procedure well, transferred to PACU,stable condition. Transferred to floor for recovery. Dc'd in stable condition on 29Nov2020, feeling well, tolerating diet, ambulating with pain controlled and recomm. f/u with pcp. Denied complications or new meds r/t SAE, incl. not taking meds for pain control. Followed up with PCP on 17Dec2020 with no further concerns. Returned to baseline health and activity. Will close SAE' reason for change: New Information		
User closed query 'PV Query: Thank you for confirming COVID tested was performed. Please provide results of COVID test. If unavailable, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:53:05
User closed query 'Per DM CLR: Per SAE Narrative "64 YR OLD WOMAN WITH H/O HTN, GERD AND INSOMNIA WHO AT HER MONTHLY PHONE CALL". However, Hypertension is not recorded in the MH eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:45:11
Query 'PV Query: Thank you for confirming COVID tested was performed. Please provide results of COVID test. If unavailable, please state so in your response.' answered with 'Test result negative, unknown if PCR. Medical records request sent to hospital multiple times with no respnse' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:52:31
Query 'Per DM CLR: Per SAE Narrative "64 YR OLD WOMAN WITH H/O HTN, GERD AND INSOMNIA WHO AT HER MONTHLY PHONE CALL". However, Hypertension is not recorded in the MH eCRF. Update as appropriate. Otherwise, provide clarification.' answered with 'HTN is now subjects medical history (new diagnosis) but noted as an AE for study since diagnosis after study start' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:22:11
User opened query 'Per DM CLR: Per SAE Narrative "64 YR OLD WOMAN WITH H/O HTN, GERD AND INSOMNIA WHO AT HER MONTHLY PHONE CALL". However, Hypertension is not recorded in the MH eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:55:49



US3312291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for confirming COVID tested was performed. Please provide results of COVID test. If unavailable, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:13:53
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 15:44:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Medical records not available. Multiple attempts made to out of state hospital to no avail. Site will not continue to attempt' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:53:09
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 14:42:07
User closed query 'Per DM CLR: SAE Narrative = 64 YR OLD WOMAN WITH H/O HTN. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:40:26
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Covid test per subject upon admission to hospital (11/27/20) unknown if PCR, medical records pending' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 18:44:32
Query 'Per DM CLR: SAE Narrative = 64 YR OLD WOMAN WITH H/O HTN. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'HTn diagnosed after enrollment' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:42:11

US3312291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = 64 YR OLD WOMAN WITH H/O HTN. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:36:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:44:43
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:44:32
User entered 'Subject is the source for this SAE report.64 yr old woman with h/o HTN, GERD and insomnia who at her monthly phone call on 12/21/2020 reported laparoscopic cholecystectomy (11/28/2020) related to cholecystitis. reports that while in Arizona over Thanksgiving,began having right-sided abdominal pain on 11/27/2020.went to the ER around 12:30 on 11/28/2020 where she was diagnosed with cholecystitis and underwent laparoscopic cholecystectomy that same day. was hospitalized post-operatively, overnight, and discharged the next the next morning on 11/29/2020. She denies any complications or new medications related to SAE, including not taking medication for pain control.has since followed up with her PCP on 12/17/2020 with no further concerns.At time of contact, she has returned to her baseline health and activity.This is an SAE, hospitalization (11/28/2020 to 11/29/2020), not related to IP. Medical records will be requested upon receipt of signed medical records release from subject.Will close SAE after review of medical records'	(b) (4), (b) (6)	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 20:40:28

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35

US3312291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:58:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Lower urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:33:47
Data point term sent to Coder	System	21 Dec 2020 20:56:40
User entered 'lower urinary tract infection'	(b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User entered empty.	System	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:02:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 20:55:50

US3312291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:58:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	25 Jan 2021 17:02:57
User entered '16 Dec 2020' reason for change: New Information	System	25 Jan 2021 17:02:57
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 17:02:47
User entered '16 Dec 2021' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 17:02:47
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User entered empty.	System	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

US3312291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:58:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication ' LOWER URINARY TRACT INFECTION' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 09:56:19
Query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication ' LOWER URINARY TRACT INFECTION' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' answered with 'See con med line #7. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 22:20:53
User opened query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication ' LOWER URINARY TRACT INFECTION' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 08:59:15
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:02:47
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User entered '0'	System	21 Dec 2020 20:55:50

**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35
User entered 'I'	System	21 Dec 2020 20:55:50



**US3312291**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:35

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:58:08

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	03 Sep 2020 19:58:16

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 19:59:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:59:41
Data point term sent to Coder	System	03 Sep 2020 19:58:59
User entered 'ambien'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 19:58:40

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'insomnia'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered '5'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

US3312291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

US3312291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'un UNK 2015'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	03 Sep 2020 19:58:40
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:58:40

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:58:40

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:58:40

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
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.	(b) (4) Coder Import (b) (4)	03 Sep 2020 20:00:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 20:00:43
Data point term sent to Coder	System	03 Sep 2020 19:59:59
User entered 'pantoprazole'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered '20'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	



US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

US3312291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'un UNK 2010'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	03 Sep 2020 19:59:19
	(b) (4)	

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:59:19

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:59:19

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:59:19

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
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)	11 Nov 2020 17:12:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 17:12:35
Data point term sent to Coder	System	11 Nov 2020 17:12:23
User entered 'SEASONAL INFLUENZA VACCINE'	(b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'SEASONAL INFLUENZA PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'INJECTION'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User entered empty.	System	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User entered empty.	System	11 Nov 2020 17:11:27

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:02
User entered empty.	System	11 Nov 2020 17:11:27



US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 19:10:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 19:10:48
Data point term sent to Coder	System	13 Nov 2020 19:10:33
User entered 'Lisinopril/ Hydrochlorothiazide'	(b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '10/12.5'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:32:29
User closed query 'Per CDM Re-query: Previous response noted, however AE#6 has a stop date of 10Nov2020 and this medication is ongoing, please review and reconcile or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 12:05:02
Query 'Per CDM Re-query: Previous response noted, however AE#6 has a stop date of 10Nov2020 and this medication is ongoing, please review and reconcile or comment accordingly. ' answered with 'correct as entered' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 20:59:31
User opened query 'Per CDM Re-query: Previous response noted, however AE#6 has a stop date of 10Nov2020 and this medication is ongoing, please review and reconcile or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:43:35
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:43:35
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' answered with 'CORRESPONDS WITH AE #6' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 16:49:49
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 14:57:11

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:10:25

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:32:29
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:10:25



US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User entered '1'	System	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User entered '1'	System	13 Nov 2020 19:10:25

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:04
User entered '804 (804)'	System	13 Nov 2020 19:10:25

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 21:30:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 21:30:51
Data point term sent to Coder	System	22 Dec 2020 21:30:04
User entered 'shingrix'	(b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'shingles prophylaxis'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0.5'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User entered empty.	System	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User entered empty.	System	22 Dec 2020 21:29:20

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:08
User entered empty.	System	22 Dec 2020 21:29:20

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	22 Dec 2020 21:31:54
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	22 Dec 2020 21:31:54
Data point term sent to Coders	System	22 Dec 2020 21:31:05
User entered 'Losartan'	(b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '12.5'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User entered '1'	System	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User entered '1'	System	22 Dec 2020 21:30:50

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:12
User entered '804 (804)'	System	22 Dec 2020 21:30:50

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:15:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:15:58
Data point term sent to Coder	System	08 Apr 2021 17:31:09
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 17:30:22
User entered '(BACTRIM DS) SULFAMETHOXAZOLE 800MG/ TRIMETHOPRIM 160MG' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:30:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 21:20:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 21:20:09
Data point term sent to Coder	System	25 Jan 2021 17:02:19
Data point term sent to Coder	System	25 Jan 2021 17:01:18
User entered '(bactrim ds) sulfamethoxazole 800MG/ trimethoprim 100MG'	(b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44



US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 17:00:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 17:00:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:00:40
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Lower URINARY TRACT INFECTION' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 17:01:54
User entered 'urinary tract infection'	(b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Per DM CLR: Please review the dose recorded in the medication name as this is not the standard dosage for this medication (consider: 800mg/160mg). Please correct the strength or provide explanation for alternate dose.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:32
Query 'Per DM CLR: Please review the dose recorded in the medication name as this is not the standard dosage for this medication (consider: 800mg/160mg). Please correct the strength or provide explanation for alternate dose.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:30:34
User opened query 'Per DM CLR: Please review the dose recorded in the medication name as this is not the standard dosage for this medication (consider: 800mg/160mg). Please correct the strength or provide explanation for alternate dose.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 02:28:00
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21



US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User entered '1'	System	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User entered '1'	System	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:15
User entered '804 (804)'	System	25 Jan 2021 17:00:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Jan 2021 16:56:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 21:31:21

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:17:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:17:36
Data point term sent to Coder	System	30 Mar 2021 18:33:35
User entered 'Ketorolac'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'cholecystitis'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '30'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'mg (mg)'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:33:04



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once (ONCE)'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Intramuscular (INTRAMUSCULAR)'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '28 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '28 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:33:04



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	Heather Barker (b) (4)	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User entered empty.	System	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User entered empty.	System	30 Mar 2021 18:33:04

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:18
User entered empty.	System	30 Mar 2021 18:33:04

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:18:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:18:31
Data point term sent to Coder	System	30 Mar 2021 18:35:37
User entered 'bismuth sbusalicylate'	Heather Barker (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'cholecystitis'	Heather Barker (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '30'	Heather Barker (b) (4)	30 Mar 2021 18:35:08



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'mL (mL)'	Heather Barker (b) (4)	30 Mar 2021 18:35:08

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once (ONCE)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:35:08

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Oral (ORAL)'	Heather Barker (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '27 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	Heather Barker (b) (4)	30 Mar 2021 18:35:08



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '27 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User entered empty.	System	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User entered empty.	System	30 Mar 2021 18:35:08

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:22
User entered empty.	System	30 Mar 2021 18:35:08

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID; CITRIC ACID; SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 07:24:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:24:34
Data point term sent to Coder	System	30 Mar 2021 18:37:38
User entered 'aspirin/citric acid/sodium bicarbonate'	Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'cholecystitis'	Heather Barker (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '2'	Heather Barker (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'tablet (TABLET)'	Heather Barker (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once (ONCE)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Oral (ORAL)'	Heather Barker (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '27 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '27 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	Heather Barker (b) (4)	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User entered empty.	System	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User entered empty.	System	30 Mar 2021 18:37:17

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:26
User entered empty.	System	30 Mar 2021 18:37:17



US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 08:05:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:05:30
Data point term sent to Coder	System	30 Mar 2021 18:38:40
User entered 'NAPROXEN SODIUM'	Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'CHOLECYSTITIS'	Heather Barker (b) (4)	30 Mar 2021 18:38:37

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:41
' (Site from DM).		
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	08 Apr 2021 17:31:53
' answered with 'updated' (Site from DM).		
User entered '220' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:31:48
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	05 Apr 2021 16:22:06
' (Site from DM).		
User entered '1'	Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:31:48
User entered 'tablet (TABLET)'	Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'once (ONCE)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'Oral (ORAL)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '27 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '0'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered '27 Nov 2020'	Heather Barker (b) (4)	30 Mar 2021 18:38:37

US3312291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:55
User entered 'No (N)'	(b) (4) Heather Barker (b) (4) (b) (4)	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User entered empty.	System	30 Mar 2021 18:38:37



**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User entered empty.	System	30 Mar 2021 18:38:37

**US3312291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:13:29
User entered empty.	System	30 Mar 2021 18:38:37

US3312291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:58:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:58:35

US3312291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered '28 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 20:22:27
	(b) (4)	
User entered '24 Nov 2020'	(b) (4), (b) (6)	21 Dec 2020 20:59:12

US3312291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'laparoscopic cholecystectomy'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:59:12

US3312291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User closed query 'Per CDML Indication is "adverse event", however the Procedure date is prior to the onset of AE. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:01:43
Query 'Per CDML Indication is "adverse event", however the Procedure date is prior to the onset of AE. Please review and clarify or update accordingly. ' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 20:22:33
User opened query 'Per CDML Indication is "adverse event", however the Procedure date is prior to the onset of AE. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:10:38
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Dec 2020 20:59:12

US3312291

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:58:08**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:59:12

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'USA-US300-2020-MRNA-1273-P301000025'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Carlos'	System	22 Dec 2020 17:45:29



US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Fierro'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '16300 College Blvd'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Shawnee'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'KS'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '66219'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered 'US'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 16:35:08
User entered '4'	System	31 Mar 2021 13:21:24
User entered '3'	System	18 Mar 2021 14:53:33
User entered '2'	System	10 Feb 2021 14:42:45
User entered '1'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'USA-US300-2020-MRNA-1273-P301000025'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Carlos'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Fierro'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '16300 College Blvd'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Shawnee'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'KS'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '66219'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered 'US'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 16:35:08
User entered '4'	System	31 Mar 2021 13:21:24
User entered '3'	System	18 Mar 2021 14:53:33
User entered '2'	System	10 Feb 2021 14:42:45
User entered '1'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '22/Dec/2020 11:57'	(b) (4) System	22 Dec 2020 17:57:23



US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:58:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 17:57:23
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 17:56:42

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'USA-US300-2020-MRNA-1273-P301000025'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Carlos'	System	22 Dec 2020 17:45:29

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Fierro'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '16300 College Blvd'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Shawnee'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'KS'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '66219'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered 'US'	System	22 Dec 2020 17:57:23



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 16:35:08
User entered '4'	System	31 Mar 2021 13:21:24
User entered '3'	System	18 Mar 2021 14:53:33
User entered '2'	System	10 Feb 2021 14:42:45
User entered '1'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '10/Feb/2021 09:42'	(b) (4) System	10 Feb 2021 14:42:45

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:58:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 14:48:02
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 14:42:45

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'USA-US300-2020-MRNA-1273-P301000025'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Carlos'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Fierro'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '16300 College Blvd'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Shawnee'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'KS'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '66219'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered 'US'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 16:35:08
User entered '4'	System	31 Mar 2021 13:21:24
User entered '3'	System	18 Mar 2021 14:53:33
User entered '2'	System	10 Feb 2021 14:42:45
User entered '1'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '18/Mar/2021 09:53'	(b) (4) System	18 Mar 2021 14:53:33

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:58:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:34:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:53:33

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'USA-US300-2020-MRNA-1273-P301000025'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Carlos'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Fierro'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '16300 College Blvd'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Shawnee'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'KS'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '66219'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered 'US'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 16:35:08
User entered '4'	System	31 Mar 2021 13:21:24
User entered '3'	System	18 Mar 2021 14:53:33
User entered '2'	System	10 Feb 2021 14:42:45
User entered '1'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
	(b) (4)	
User entered '30/Mar/2021 14:37'	Heather Barker (b) (4)	30 Mar 2021 19:37:17
	(b) (4)	

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:58:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:34:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:21:24

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'USA-US300-2020-MRNA-1273-P301000025'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Carlos'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Fierro'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '16300 College Blvd'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Shawnee'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'KS'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '66219'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered 'US'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 16:35:08
User entered '4'	System	31 Mar 2021 13:21:24
User entered '3'	System	18 Mar 2021 14:53:33
User entered '2'	System	10 Feb 2021 14:42:45
User entered '1'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered '31/Mar/2021 06:21'	(b) (4) System	31 Mar 2021 13:21:24



US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:58:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:34:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:21:24

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'USA-US300-2020-MRNA-1273-P301000025'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Yes (Y)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'No (N)'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Carlos'	System	22 Dec 2020 17:45:29

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Fierro'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '16300 College Blvd'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'Shawnee'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered 'KS'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:56:37
User entered '66219'	System	22 Dec 2020 17:45:29

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:42:33
User entered 'US'	System	22 Dec 2020 17:57:23



**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 16:35:08
User entered '4'	System	31 Mar 2021 13:21:24
User entered '3'	System	18 Mar 2021 14:53:33
User entered '2'	System	10 Feb 2021 14:42:45
User entered '1'	System	22 Dec 2020 17:57:23

**US3312291**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000025**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 16:58:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:56:08
User entered '09/Apr/2021 12:35'	(b) (4) System	09 Apr 2021 16:35:08

US3312291

Folder: SAE USA-US300-2020-MRNA-1273-P301000025

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:58:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:56:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:35:08