

US3312551 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

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US3312551

Form: Participant Creation

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Participant ID

US3312551

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

US3312551

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	28
Age Units	YEARS
Age (Derived)	28
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) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Date of Informed Consent (<i>dd MMM yyyy</i>)	8 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 20:53:24

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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) 23 Feb 2021 20:53:24

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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) 23 Feb 2021 20:53:24

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Condition	DYSMENORRHEA
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Condition	ANXIETY
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: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:53:24

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:08 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 15:08
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	154 lb
BMI (<i>xxx.x</i>)	27.33692 kg/m ²
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) 23 Feb 2021 20:53:24

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 20:53:24

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Date of assessment (dd MMM yyyy) 08 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
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: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:53:24

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	08 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 20:53:24

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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 ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 20:53:24

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	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) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 20:53:27

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What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 112519

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) 23 Feb 2021 20:53:27

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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) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	15:08 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 15:08
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	16:51 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 16:51
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:53:24

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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: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 SEP 2020

What was the treatment time? (00:00-23:59) 16:20 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 16:20

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) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	15:47 (24 HR)
Collection date and time (derived)	08 SEP 2020 15:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:42	08 SEP 2020 15:42
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 16:51

PC Open Date & Time

08 SEP 2020 16:40

PC Close Date & Time

08 SEP 2020 19:10

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 21:03

PC Open Date & Time

08 SEP 2020 20:05

PC Close Date & Time

09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:08

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 SEP 2020 23:35

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 19:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

13 SEP 2020 18:34

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 16:51

PC Open Date & Time

08 SEP 2020 16:40

PC Close Date & Time

08 SEP 2020 19:10

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 21:03

PC Open Date & Time

08 SEP 2020 20:05

PC Close Date & Time

09 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:09

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 19:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 23:35

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 19:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:35

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 20:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 16:52
PC Open Date & Time	08 SEP 2020 16:40
PC Close Date & Time	08 SEP 2020 19:10

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 21:04
PC Open Date & Time	08 SEP 2020 20:05
PC Close Date & Time	09 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:10
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 23:35
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

		Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 18:35	
PC Open Date & Time	13 SEP 2020 12:00	
PC Close Date & Time	14 SEP 2020 11:59	

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:11
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312551

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	08:27 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 08:27
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	10:29 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:29
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3312551

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	8 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 OCT 2020

What was the treatment time? (00:00-23:59) 09:58 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 09:58

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

US3312551

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

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

Collection date (dd MMM yyyy)	8 OCT 2020
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Collection time (00:00-23:59)	09:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	8 OCT 2020 09:20
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US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:09	8 OCT 2020 09:09
Nasopharyngeal Swab 2	No		

US3312551

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

08 OCT 2020 10:33

PC Open Date & Time

08 OCT 2020 10:18

PC Close Date & Time

08 OCT 2020 12:48

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

100.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	08 OCT 2020 20:15
PC Open Date & Time	08 OCT 2020 13:43
PC Close Date & Time	09 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

102.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 OCT 2020 21:36

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 22:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

11 OCT 2020 18:51

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp 12 OCT 2020 19:28

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 21:32

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 20:58

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 10:33

PC Open Date & Time

08 OCT 2020 10:18

PC Close Date & Time

08 OCT 2020 12:48

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 20:15

PC Open Date & Time

08 OCT 2020 13:43

PC Close Date & Time

09 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 21:44

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 22:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 18:51

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 19:29

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 21:35

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 20:58

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 10:34
PC Open Date & Time	08 OCT 2020 10:18
PC Close Date & Time	08 OCT 2020 12:48

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 20:16
PC Open Date & Time	08 OCT 2020 13:43
PC Close Date & Time	09 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 21:47
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 22:03
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 18:52
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 19:29
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 21:36
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 20:59
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 19:52
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 21:32
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 20:28
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 18:43
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

20 OCT 2020 20:00

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 20:00
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 20:00
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 20:09
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 17

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

No ☒

Yes ☐

PC Time stamp

24 OCT 2020 20:10

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 20:00
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 20:09
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 20

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

No ☒

Yes ☐

PC Time stamp

27 OCT 2020 19:48

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 OCT 2020 20:00
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 OCT 2020 20:00
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 19:57
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 24

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

No ☒

Yes ☐

PC Time stamp

31 OCT 2020 20:09

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 NOV 2020 20:21
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 NOV 2020 20:03
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 27

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

No ☒

Yes ☐

PC Time stamp

04 NOV 2020 05:59

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 NOV 2020 21:25
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 NOV 2020 22:06
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 NOV 2020 20:00
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 31

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

No ☒

Yes ☐

PC Time stamp

07 NOV 2020 12:00

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 NOV 2020 12:05
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 33

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

No ☒

Yes ☐

PC Time stamp

09 NOV 2020 19:12

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 34

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

No ☒

Yes ☐

PC Time stamp

10 NOV 2020 19:59

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 35
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 NOV 2020 21:13
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 36
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 NOV 2020 20:00
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 37

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

No ☒

Yes ☐

PC Time stamp

13 NOV 2020 20:02

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 38

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

No ☒

Yes ☐

PC Time stamp

14 NOV 2020 22:35

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 39

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

No ☒

Yes ☐

PC Time stamp

15 NOV 2020 20:00

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 40
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 NOV 2020 20:00
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 41
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 NOV 2020 21:30
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 42
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 NOV 2020 20:01
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 43

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

No ☐

Yes ☒

PC Time stamp

19 NOV 2020 20:00

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 44
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 NOV 2020 20:00
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 45

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

No ☒

Yes ☐

PC Time stamp

21 NOV 2020 20:02

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 46
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 NOV 2020 20:00
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 47

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

No ☒

Yes ☐

PC Time stamp

23 NOV 2020 21:39

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 48
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 NOV 2020 21:48
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 49
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 NOV 2020 20:12
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 50

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

No ☒

Yes ☐

PC Time stamp

26 NOV 2020 21:26

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 51

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

No ☒

Yes ☐

PC Time stamp

28 NOV 2020 09:35

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 52

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 53

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

No ☒

Yes ☐

PC Time stamp

29 NOV 2020 12:00

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 54

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

No ☒

Yes ☐

PC Time stamp

30 NOV 2020 20:01

PC Open Date & Time

30 NOV 2020 12:00

PC Close Date & Time

01 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 55

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

No ☒

Yes ☐

PC Time stamp

01 DEC 2020 20:00

PC Open Date & Time

01 DEC 2020 12:00

PC Close Date & Time

02 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 56
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 DEC 2020 06:27
PC Open Date & Time	02 DEC 2020 12:00
PC Close Date & Time	03 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 57

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

No ☒

Yes ☐

PC Time stamp

03 DEC 2020 12:00

PC Open Date & Time

03 DEC 2020 12:00

PC Close Date & Time

04 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 58

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

No ☐

Yes ☒

PC Time stamp

04 DEC 2020 21:20

PC Open Date & Time

04 DEC 2020 12:00

PC Close Date & Time

05 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 59

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

No ☒

Yes ☐

PC Time stamp

05 DEC 2020 20:16

PC Open Date & Time

05 DEC 2020 12:00

PC Close Date & Time

06 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 60
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 DEC 2020 20:00
PC Open Date & Time	06 DEC 2020 12:00
PC Close Date & Time	07 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 61
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 DEC 2020 17:22
PC Open Date & Time	07 DEC 2020 12:00
PC Close Date & Time	08 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 62
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 DEC 2020 21:25
PC Open Date & Time	08 DEC 2020 12:00
PC Close Date & Time	09 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 8

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 15 OCT 2020 19:52

PC Open Date and Time 15 OCT 2020 12:00

PC Close Date and Time 16 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 9

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 16 OCT 2020 21:32

PC Open Date and Time 16 OCT 2020 12:00

PC Close Date and Time 17 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 10

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 20:28

PC Open Date and Time

17 OCT 2020 12:00

PC Close Date and Time

18 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 11

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 18 OCT 2020 18:44

PC Open Date and Time 18 OCT 2020 12:00

PC Close Date and Time 19 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 12

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 19 OCT 2020 20:00

PC Open Date and Time 19 OCT 2020 12:00

PC Close Date and Time 20 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(13)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 13

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 20 OCT 2020 20:00

PC Open Date and Time 20 OCT 2020 12:00

PC Close Date and Time 21 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(14)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 14

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 21 OCT 2020 20:01

PC Open Date and Time 21 OCT 2020 12:00

PC Close Date and Time 22 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(15)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 15

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 22 OCT 2020 20:00

PC Open Date and Time 22 OCT 2020 12:00

PC Close Date and Time 23 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(16)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 16

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 23 OCT 2020 20:09

PC Open Date and Time 23 OCT 2020 12:00

PC Close Date and Time 24 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(17)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 17

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 24 OCT 2020 20:10

PC Open Date and Time 24 OCT 2020 12:00

PC Close Date and Time 25 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(18)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 18

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 OCT 2020 20:00

PC Open Date and Time 25 OCT 2020 12:00

PC Close Date and Time 26 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(19)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 19

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 OCT 2020 20:09

PC Open Date and Time 26 OCT 2020 12:00

PC Close Date and Time 27 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(20)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 20

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 OCT 2020 19:48

PC Open Date and Time

27 OCT 2020 12:00

PC Close Date and Time

28 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(21)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 21

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 OCT 2020 20:00

PC Open Date and Time 28 OCT 2020 12:00

PC Close Date and Time 29 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(22)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 22

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 OCT 2020 20:01

PC Open Date and Time 29 OCT 2020 12:00

PC Close Date and Time 30 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(23)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 23

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 OCT 2020 19:57

PC Open Date and Time 30 OCT 2020 12:00

PC Close Date and Time 31 OCT 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(24)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 24

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 OCT 2020 20:09

PC Open Date and Time

31 OCT 2020 12:00

PC Close Date and Time

01 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(25)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 25

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 NOV 2020 20:21

PC Open Date and Time 01 NOV 2020 12:00

PC Close Date and Time 02 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(26)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 26

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 02 NOV 2020 20:03

PC Open Date and Time 02 NOV 2020 12:00

PC Close Date and Time 03 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(27)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 27

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 04 NOV 2020 05:59

PC Open Date and Time 03 NOV 2020 12:00

PC Close Date and Time 04 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(28)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 28

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

04 NOV 2020 21:25

PC Open Date and Time

04 NOV 2020 12:00

PC Close Date and Time

05 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(29)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 29

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 05 NOV 2020 22:06

PC Open Date and Time 05 NOV 2020 12:00

PC Close Date and Time 06 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(30)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 30

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

PC Open Date and Time

06 NOV 2020 12:00

PC Close Date and Time

07 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(31)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 31

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 07 NOV 2020 12:00

PC Open Date and Time 07 NOV 2020 12:00

PC Close Date and Time 08 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(32)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 32

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 NOV 2020 12:05

PC Open Date and Time

08 NOV 2020 12:00

PC Close Date and Time

09 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(33)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 33

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 NOV 2020 19:12

PC Open Date and Time

09 NOV 2020 12:00

PC Close Date and Time

10 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(34)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 34

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 10 NOV 2020 20:00

PC Open Date and Time 10 NOV 2020 12:00

PC Close Date and Time 11 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(35)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 35

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 11 NOV 2020 21:13

PC Open Date and Time 11 NOV 2020 12:00

PC Close Date and Time 12 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(36)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 36

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 12 NOV 2020 20:00

PC Open Date and Time 12 NOV 2020 12:00

PC Close Date and Time 13 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(37)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 37

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 13 NOV 2020 20:02

PC Open Date and Time 13 NOV 2020 12:00

PC Close Date and Time 14 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(38)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 38

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 14 NOV 2020 22:36

PC Open Date and Time 14 NOV 2020 12:00

PC Close Date and Time 15 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(39)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 39

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 15 NOV 2020 20:00

PC Open Date and Time 15 NOV 2020 12:00

PC Close Date and Time 16 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(40)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 40

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 16 NOV 2020 20:00

PC Open Date and Time 16 NOV 2020 12:00

PC Close Date and Time 17 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(41)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 41

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 17 NOV 2020 21:31

PC Open Date and Time 17 NOV 2020 12:00

PC Close Date and Time 18 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(42)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 42

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 18 NOV 2020 20:01

PC Open Date and Time 18 NOV 2020 12:00

PC Close Date and Time 19 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(43)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 43

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 19 NOV 2020 20:00

PC Open Date and Time 19 NOV 2020 12:00

PC Close Date and Time 20 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(44)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 44

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 20 NOV 2020 20:00

PC Open Date and Time 20 NOV 2020 12:00

PC Close Date and Time 21 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(45)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 45

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 NOV 2020 20:02

PC Open Date and Time

21 NOV 2020 12:00

PC Close Date and Time

22 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(46)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 46

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 22 NOV 2020 20:00

PC Open Date and Time 22 NOV 2020 12:00

PC Close Date and Time 23 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(47)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 47

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 23 NOV 2020 21:39

PC Open Date and Time 23 NOV 2020 12:00

PC Close Date and Time 24 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(48)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 48

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 24 NOV 2020 21:48

PC Open Date and Time 24 NOV 2020 12:00

PC Close Date and Time 25 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(49)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 49

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 NOV 2020 20:12

PC Open Date and Time 25 NOV 2020 12:00

PC Close Date and Time 26 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(50)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 50

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 NOV 2020 21:26

PC Open Date and Time 26 NOV 2020 12:00

PC Close Date and Time 27 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(51)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 51

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 NOV 2020 09:35

PC Open Date and Time 27 NOV 2020 12:00

PC Close Date and Time 28 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(52)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 52

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

PC Open Date and Time

28 NOV 2020 12:00

PC Close Date and Time

29 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(53)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 53

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 NOV 2020 12:00

PC Open Date and Time 29 NOV 2020 12:00

PC Close Date and Time 30 NOV 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(54)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 54

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 NOV 2020 20:01

PC Open Date and Time 30 NOV 2020 12:00

PC Close Date and Time 01 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(55)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 55

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 DEC 2020 20:00

PC Open Date and Time

01 DEC 2020 12:00

PC Close Date and Time

02 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(56)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 56

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 03 DEC 2020 06:28

PC Open Date and Time 02 DEC 2020 12:00

PC Close Date and Time 03 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(57)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 57

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 03 DEC 2020 12:00

PC Open Date and Time 03 DEC 2020 12:00

PC Close Date and Time 04 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(58)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 58

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 04 DEC 2020 21:20

PC Open Date and Time 04 DEC 2020 12:00

PC Close Date and Time 05 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(59)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 59

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 05 DEC 2020 20:16

PC Open Date and Time 05 DEC 2020 12:00

PC Close Date and Time 06 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(60)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 60

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

06 DEC 2020 20:00

PC Open Date and Time

06 DEC 2020 12:00

PC Close Date and Time

07 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(61)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 61

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

07 DEC 2020 17:22

PC Open Date and Time

07 DEC 2020 12:00

PC Close Date and Time

08 DEC 2020 11:59

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(62)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 62

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 08 DEC 2020 21:26

PC Open Date and Time 08 DEC 2020 12:00

PC Close Date and Time 09 DEC 2020 11:59

US3312551

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:24

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 10:36
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312551

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3312551

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

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

Collection date (dd MMM yyyy)	05 NOV 2020
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Collection time (00:00-23:59)	11:17 (24 HR)
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Collection date and time (derived)	05 NOV 2020 11:17
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US3312551

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:53:27

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 12:06:00

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 06:30:32

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

20 NOV 2020 20:00:43

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 21:26:28
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 06:28:25

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 DEC 2020 16:50:24
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 18:41:06
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 17:59:34
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 06:22:10

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 17:59:18
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 06:46:35
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 12:00:35

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 19:56:06

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 18:11:28

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 15:37:33

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 FEB 2021 21:22:13
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 18:50:04

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 06:20:36
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	20 MAR 2021 12:00:16
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 07:35:24

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 12:01:02

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 20:04:20

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 06:20:30

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 14:57:47

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	29 APR 2021 15:13:19
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 257

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

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

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

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

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 278

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 306

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 474

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 495

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 579

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

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

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

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

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 642

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

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28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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15 AUG 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 719

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

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

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05 SEP 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

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08 SEP 2022 00:01

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12 SEP 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

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26 SEP 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

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03 OCT 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

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

Patient Cloud Open Date & Time	10 NOV 2022 00:01
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Patient Cloud Close Date & Time	14 NOV 2022 23:59
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US3312551

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:20:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 18:50:14

US3312551

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:17:47

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:17:47

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:17:47

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312551

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

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

Visit date (dd MMM yyyy)	25 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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US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

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) _____

US3312551

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3312551

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

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

Collection date (dd MMM yyyy)	25 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:59 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	25 MAR 2021 10:59
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US3312551

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:17:48

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312551

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312551

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:20:12

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312551

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

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

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

Visit date (dd MMM yyyy)	25 MAR 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3312551

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

Form: Unblinding

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Date of updated informed consent (dd MMM yyyy) 25 MAR 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 28 DEC 2020

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3312551

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

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

Collection date (dd MMM yyyy)	25 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:59 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	25 MAR 2021 10:59
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US3312551

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00 - 23:59)	10:58
Collection Date and Time (derived)	25 MAR 2021 10:58

US3312551

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 15:19:15

Generated On: 11 Aug 2021 22:20:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312551

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 19:25:17

Generated On: 11 Aug 2021 22:20:12

AEID

Adverse event

IPSILATERAL UNDERARM
GLAND TENDERNESS
(LYMPHADENOPATHY)

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 14 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

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EAB) (1725)

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US3312551

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 19:25:17

Generated On: 11 Aug 2021 22:20:12

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

US3312551

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 19:25:17

Generated On: 11 Aug 2021 22:20:12

AEID

Adverse event

IPSILATERAL UNDERARM
GLAND SWELLING

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 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 (2)

Data signed: (b) (4) 07 Apr 2021 19:25:17

Generated On: 11 Aug 2021 22:20:12

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 19:25:17

Generated On: 11 Aug 2021 22:20:12

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 (3)

Data signed: (b) (4) 07 Apr 2021 19:25:17

Generated On: 11 Aug 2021 22:20:12

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) 08 Apr 2021 15:19:15

Generated On: 11 Aug 2021 22:20:12

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication DYSMENORRHEA

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Name of Medication NUVA RING (ETHINYL
ESTRADIOL/ ETONOGESTREL)

Prophylaxis Yes ☒
No ☐

Indication PREGNANCY PROPHYLAXIS

Dose per administration 0.015/0.12

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAVAGINAL	
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" 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) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

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 (4)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

	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)	23 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)		23 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 (5)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 18:17:19

Generated On: 11 Aug 2021 22:20:12

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:20:12

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:20:12

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3312551 (Prod: Johnson County Clin-Trials)

US3312551

Form: Participant Creation

Generated On: 11 Aug 2021 22:20:12

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'US3312551'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:59:23

US3312551

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:47:06
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:09:12
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:14:44
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 21:23:18

US3312551

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:59:24

US3312551

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[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 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	08 Sep 2020 21:23:18

US3312551

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'SCRN'	System	08 Sep 2020 21:23:18

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered (b) (6) 1991'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:59:25

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '28'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'YEARS'	System	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered '28'	System	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Female (F)'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'I'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:20:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 21:23:31

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '8 Sep 2020'	Christa Estrada (b) (4)	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'Sep 2020'	System	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered '2020'	System	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4)	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	Christa Estrada (b) (4)	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	Christa Estrada (b) (4)	08 Sep 2020 21:23:44

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:59:24

US3312551

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:20:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'I'	System	08 Sep 2020 21:23:54

US3312551

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:20:12

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	Christa Estrada (b) (4)	08 Sep 2020 21:23:54

US3312551

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:20:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:03:43

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Dysmenorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 20:04:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 20:04:53
Data point term sent to Coder	System	29 Sep 2020 20:04:06
User entered 'dysmenorrhea'	Karol Moore (b) (4)	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'Jan 2006'	System	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered '2006'	System	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered empty.	System	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:20:12

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered empty.	System	29 Sep 2020 20:04:01

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 17:50:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 17:50:05
Data point term sent to Coder	System	20 Jan 2021 17:49:38
User entered 'anxiety'	(b) (4), (b) (6)	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'Jan 2015'	System	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered '2015'	System	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered empty.	System	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:20:12

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered empty.	System	20 Jan 2021 17:49:06

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '15:08'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered '08 Sep 2020 15:08'	System	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '63' in	(b) (4)	29 Sep 2020 20:04:19
DataPoint set to visible.	Karol Moore (b) (4)	08 Sep 2020 21:23:54
	(b) (4)	
	System	

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '154' lb	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:19
DataPoint set to visible.	(b) (4) System	08 Sep 2020 21:23:54

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered '27.33692'	System	29 Sep 2020 20:04:19
DataPoint set to visible.	System	08 Sep 2020 21:23:54

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'kg/m2'	System	29 Sep 2020 20:04:19
DataPoint set to visible.	System	08 Sep 2020 21:23:54

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'bpm'	System	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'breaths/min'	System	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'mmHg'	System	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered 'mmHg'	System	29 Sep 2020 20:04:19

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39

US3312551

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39

US3312551

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:32

US3312551

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:32

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:20:12

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:04:52

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Negative (NEGATIVE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User entered empty.	System	29 Sep 2020 20:05:50

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

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 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

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 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4)	29 Sep 2020 20:05:36
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4)	29 Sep 2020 20:05:36
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '0'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:20:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:20:39
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:05:36

US3312551

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:04

US3312551

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Sep 2020'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:04

US3312551

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[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 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	08 Sep 2020 21:24:04

US3312551

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'VISIT1'	System	08 Sep 2020 21:24:04

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 21:04:33

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '112519'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 21:04:33

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 21:04:33

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	Christa Estrada (b) (4)	08 Sep 2020 21:24:15

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	Christa Estrada (b) (4)	08 Sep 2020 21:24:15

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:15

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:15

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:15

US3312551

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:20:12

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:00
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:43:13
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:43:13

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:20:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:20:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:20:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:20:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	29 Sep 2020 20:06:48
	(b) (4)	

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '15:08'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered '08 Sep 2020 15:08'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '98.5' F	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '77'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'bpm'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'breaths/min'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '120'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'mmHg'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '80'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'mmHg'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:20:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:20:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '16:51'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered '08 Sep 2020 16:51'	System	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '99.1' F	(b) (4)	29 Sep 2020 20:06:48
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '71'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'bpm'	System	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'breaths/min'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '109'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'mmHg'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '76'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'mmHg'	System	29 Sep 2020 20:06:48

US3312551

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:54

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:54

US3312551

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:58

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:58

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:58

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:58

US3312551

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:06:58

US3312551

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:58

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:06:58

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered empty.	System	29 Sep 2020 20:06:58

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 21:24:35

US3312551

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 21:24:35

US3312551

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:12:33
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Heather Barker (b) (4)	21 Oct 2020 18:40:06
' answered with 'updated' (Site from DM).	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Heather Barker (b) (4)	21 Oct 2020 18:39:56
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	14 Oct 2020 15:38:54
' (Site from DM).		
User entered '8 Sep 2020'	Christa Estrada (b) (4)	08 Sep 2020 21:24:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '16:20'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 21:24:35

US3312551

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered '08 Sep 2020 16:20'	System	21 Oct 2020 18:39:56
User entered '8 Sep 2020 16:20'	System	08 Sep 2020 21:24:35

US3312551

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	08 Sep 2020 21:24:35

US3312551

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'ONCE'	System	08 Sep 2020 21:24:35

US3312551

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 21:24:35

US3312551

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:24

US3312551

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:24

US3312551

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '15:47'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:24

US3312551

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered '08 Sep 2020 15:47'	System	29 Sep 2020 20:07:24

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '15:42'	(b) (4)	29 Sep 2020 20:07:34
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered '08 Sep 2020 15:42'	System	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered empty.	System	29 Sep 2020 20:07:34

US3312551

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:37

US3312551

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'I'	System	29 Sep 2020 20:07:37

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:50:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '490a1c7a-5c95-4ab5-8083-b624749b4d1a' User entered 'Yes (Y)'	System	08 Sep 2020 21:51:04
	System	08 Sep 2020 21:51:04

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:50:45', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '490a1c7a-5c95-4ab5-8083-b624749b4d1a' User entered '99.1'	System	08 Sep 2020 21:51:04
	System	08 Sep 2020 21:51:04

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:50:55', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '490a1c7a-5c95-4ab5-8083-b624749b4d1a' User entered 'No (N)'	System	08 Sep 2020 21:51:04
	System	08 Sep 2020 21:51:04

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '490a1c7a-5c95-4ab5-8083-b624749b4d1a' User entered '08 Sep 2020 16:51'	System	08 Sep 2020 21:51:04
	System	08 Sep 2020 21:51:04

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 16:40'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 19:10'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:02:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bb547ad-f328-49b5-a2aa-974808a43fb4' User entered 'Yes (Y)'	System	09 Sep 2020 02:03:10
	System	09 Sep 2020 02:03:10

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:02:55', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bb547ad-f328-49b5-a2aa-974808a43fb4' User entered '98.1'	System	09 Sep 2020 02:03:10
	System	09 Sep 2020 02:03:10

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:02:59', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bb547ad-f328-49b5-a2aa-974808a43fb4'	System	09 Sep 2020 02:03:10
User entered 'No (N)'	System	09 Sep 2020 02:03:10

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bb547ad-f328-49b5-a2aa-974808a43fb4' User entered '08 Sep 2020 21:03'	System	09 Sep 2020 02:03:10
	System	09 Sep 2020 02:03:10

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 20:05'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 2'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:08:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '23b801b1-b020-43c3-885b-228a7b3df519' User entered 'Yes (Y)'	System	10 Sep 2020 00:08:36
	System	10 Sep 2020 00:08:36

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:08:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '23b801b1-b020-43c3-885b-228a7b3df519' User entered '99.8'	System	10 Sep 2020 00:08:36
	System	10 Sep 2020 00:08:36

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:08:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '23b801b1-b020-43c3-885b-228a7b3df519'	System	10 Sep 2020 00:08:36
User entered 'No (N)'	System	10 Sep 2020 00:08:36

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:08:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '23b801b1-b020-43c3-885b-228a7b3df519' User entered '09 Sep 2020 19:08'	System	10 Sep 2020 00:08:36
	System	10 Sep 2020 00:08:36

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 3'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '707e5a24-7693-4302-88c3-f0c9d22b0375'	System	11 Sep 2020 00:02:17
User entered 'Yes (Y)'	System	11 Sep 2020 00:02:17

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '707e5a24-7693-4302-88c3-f0c9d22b0375' User entered '99.1'	System	11 Sep 2020 00:02:17
	System	11 Sep 2020 00:02:17

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '707e5a24-7693-4302-88c3-f0c9d22b0375'	System	11 Sep 2020 00:02:17
User entered 'No (N)'	System	11 Sep 2020 00:02:17

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:14', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '707e5a24-7693-4302-88c3-f0c9d22b0375' User entered '10 Sep 2020 19:02'	System	11 Sep 2020 00:02:17
	System	11 Sep 2020 00:02:17

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 4'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a09260fc-cc82-4259-b18c-e9b4478bf739'	System	12 Sep 2020 04:35:12
User entered 'Yes (Y)'	System	12 Sep 2020 04:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a09260fc-cc82-4259-b18c-e9b4478bf739' User entered '98.3'	System	12 Sep 2020 04:35:12
	System	12 Sep 2020 04:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a09260fc-cc82-4259-b18c-e9b4478bf739'	System	12 Sep 2020 04:35:12
User entered 'No (N)'	System	12 Sep 2020 04:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a09260fc-cc82-4259-b18c-e9b4478bf739'	System	12 Sep 2020 04:35:12
User entered '11 Sep 2020 23:35'	System	12 Sep 2020 04:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 5'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2ce62c81-cdf5-4e11-adcf-cbd466104840' User entered 'Yes (Y)'	System	13 Sep 2020 00:35:41
	System	13 Sep 2020 00:35:41

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2ce62c81-cdf5-4e11-adcf-cbd466104840' User entered '98.4'	System	13 Sep 2020 00:35:41
	System	13 Sep 2020 00:35:41

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:31', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2ce62c81-cdf5-4e11-adcf-cbd466104840'	System	13 Sep 2020 00:35:41
User entered 'No (N)'	System	13 Sep 2020 00:35:41

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2ce62c81-cdf5-4e11-adcf-cbd466104840'	System	13 Sep 2020 00:35:41
User entered '12 Sep 2020 19:35'	System	13 Sep 2020 00:35:41

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 6'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:34:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4a1587fa-09b8-4612-8759-8fcf8b9a522a' User entered 'Yes (Y)'	System	13 Sep 2020 23:34:55
	System	13 Sep 2020 23:34:55

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:34:40', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4a1587fa-09b8-4612-8759-8fcf8b9a522a' User entered '98.8'	System	13 Sep 2020 23:34:55
	System	13 Sep 2020 23:34:55

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:34:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4a1587fa-09b8-4612-8759-8fcf8b9a522a'	System	13 Sep 2020 23:34:55
User entered 'No (N)'	System	13 Sep 2020 23:34:55

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:34:52', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4a1587fa-09b8-4612-8759-8fcf8b9a522a' User entered '13 Sep 2020 18:34'	System	13 Sep 2020 23:34:55
	System	13 Sep 2020 23:34:55

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 7'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:09:07', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0504e8c-a1ad-4d3e-94af-59637fc968e6' User entered 'Yes (Y)'	System	15 Sep 2020 01:10:02
	System	15 Sep 2020 01:10:02

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:09:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0504e8c-a1ad-4d3e-94af-59637fc968e6' User entered '98.6'	System	15 Sep 2020 01:10:02
	System	15 Sep 2020 01:10:02

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:09:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0504e8c-a1ad-4d3e-94af-59637fc968e6'	System	15 Sep 2020 01:10:02
User entered 'No (N)'	System	15 Sep 2020 01:10:02

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:10:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0504e8c-a1ad-4d3e-94af-59637fc968e6'	System	15 Sep 2020 01:10:02
User entered '14 Sep 2020 20:10'	System	15 Sep 2020 01:10:02

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:12', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0e7bb91-8935-44e9-b208-12083e8e0de4'	System	08 Sep 2020 21:51:31
User entered 'None (1)'	System	08 Sep 2020 21:51:31

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:14', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0e7bb91-8935-44e9-b208-12083e8e0de4'	System	08 Sep 2020 21:51:31
User entered 'No (N)'	System	08 Sep 2020 21:51:31

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:17', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0e7bb91-8935-44e9-b208-12083e8e0de4' User entered 'No (N)'	System	08 Sep 2020 21:51:31
	System	08 Sep 2020 21:51:31

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0e7bb91-8935-44e9-b208-12083e8e0de4'	System	08 Sep 2020 21:51:31
User entered 'None (1)'	System	08 Sep 2020 21:51:31

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0e7bb91-8935-44e9-b208-12083e8e0de4' User entered '08 Sep 2020 16:51'	System	08 Sep 2020 21:51:31
	System	08 Sep 2020 21:51:31

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 16:40'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 19:10'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:17', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f7f8ba2b-ba7e-428c-9f05-e234cc71f863'	System	09 Sep 2020 02:03:55
User entered 'None (1)'	System	09 Sep 2020 02:03:55

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f7f8ba2b-ba7e-428c-9f05-e234cc71f863' User entered 'No (N)'	System	09 Sep 2020 02:03:55
	System	09 Sep 2020 02:03:55

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f7f8ba2b-ba7e-428c-9f05-e234cc71f863'	System	09 Sep 2020 02:03:55
User entered 'No (N)'	System	09 Sep 2020 02:03:55

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f7f8ba2b-ba7e-428c-9f05-e234cc71f863'	System	09 Sep 2020 02:03:55
User entered 'None (1)'	System	09 Sep 2020 02:03:55

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f7f8ba2b-ba7e-428c-9f05-e234cc71f863'	System	09 Sep 2020 02:03:55
User entered '08 Sep 2020 21:03'	System	09 Sep 2020 02:03:55

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 20:05'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 2'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:08:52', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e887d527-9529-4c5c-867b-ac1d289c0db9'	System	10 Sep 2020 00:09:14
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:09:14

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:09:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e887d527-9529-4c5c-867b-ac1d289c0db9' User entered 'No (N)'	System	10 Sep 2020 00:09:14
	System	10 Sep 2020 00:09:14

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:09:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e887d527-9529-4c5c-867b-ac1d289c0db9' User entered 'No (N)'	System	10 Sep 2020 00:09:14
	System	10 Sep 2020 00:09:14

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:09:09', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e887d527-9529-4c5c-867b-ac1d289c0db9'	System	10 Sep 2020 00:09:14
User entered 'None (1)'	System	10 Sep 2020 00:09:14

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:09:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e887d527-9529-4c5c-867b-ac1d289c0db9' User entered '09 Sep 2020 19:09'	System	10 Sep 2020 00:09:14
	System	10 Sep 2020 00:09:14

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 3'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6686718f-4b2d-4b74-9c86-9e17b8fd288e'	System	11 Sep 2020 00:02:37
User entered 'None (1)'	System	11 Sep 2020 00:02:37

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6686718f-4b2d-4b74-9c86-9e17b8fd288e' User entered 'No (N)'	System	11 Sep 2020 00:02:37
	System	11 Sep 2020 00:02:37

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6686718f-4b2d-4b74-9c86-9e17b8fd288e' User entered 'No (N)'	System	11 Sep 2020 00:02:37
	System	11 Sep 2020 00:02:37

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6686718f-4b2d-4b74-9c86-9e17b8fd288e' User entered 'None (1)'	System	11 Sep 2020 00:02:37
	System	11 Sep 2020 00:02:37

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6686718f-4b2d-4b74-9c86-9e17b8fd288e' User entered '10 Sep 2020 19:02'	System	11 Sep 2020 00:02:37
	System	11 Sep 2020 00:02:37

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 4'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '515bdc60-41ea-44f2-ad3c-90e6b413e169'	System	12 Sep 2020 04:35:24
User entered 'None (1)'	System	12 Sep 2020 04:35:24

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '515bdc60-41ea-44f2-ad3c-90e6b413e169'	System	12 Sep 2020 04:35:24
User entered 'No (N)'	System	12 Sep 2020 04:35:24

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:17', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '515bdc60-41ea-44f2-ad3c-90e6b413e169' User entered 'No (N)'	System	12 Sep 2020 04:35:24
	System	12 Sep 2020 04:35:24

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '515bdc60-41ea-44f2-ad3c-90e6b413e169'	System	12 Sep 2020 04:35:24
User entered 'None (1)'	System	12 Sep 2020 04:35:24

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '515bdc60-41ea-44f2-ad3c-90e6b413e169'	System	12 Sep 2020 04:35:24
User entered '11 Sep 2020 23:35'	System	12 Sep 2020 04:35:24

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 5'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f9e88f2-5cd2-47e6-95a7-42c7ff9e3b78'	System	13 Sep 2020 00:35:53
User entered 'None (1)'	System	13 Sep 2020 00:35:53

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f9e88f2-5cd2-47e6-95a7-42c7ff9e3b78' User entered 'No (N)'	System	13 Sep 2020 00:35:53
	System	13 Sep 2020 00:35:53

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f9e88f2-5cd2-47e6-95a7-42c7ff9e3b78'	System	13 Sep 2020 00:35:53
User entered 'No (N)'	System	13 Sep 2020 00:35:53

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f9e88f2-5cd2-47e6-95a7-42c7ff9e3b78'	System	13 Sep 2020 00:35:53
User entered 'None (1)'	System	13 Sep 2020 00:35:53

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:52', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f9e88f2-5cd2-47e6-95a7-42c7ff9e3b78'	System	13 Sep 2020 00:35:53
User entered '12 Sep 2020 19:35'	System	13 Sep 2020 00:35:53

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 6'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:34:59', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e23f8ac3-d174-4d89-9e9e-1be22c90d73f' User entered 'None (1)'	System	13 Sep 2020 23:35:12
	System	13 Sep 2020 23:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:01', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e23f8ac3-d174-4d89-9e9e-1be22c90d73f' User entered 'No (N)'	System	13 Sep 2020 23:35:12
	System	13 Sep 2020 23:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e23f8ac3-d174-4d89-9e9e-1be22c90d73f' User entered 'No (N)'	System	13 Sep 2020 23:35:12
	System	13 Sep 2020 23:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e23f8ac3-d174-4d89-9e9e-1be22c90d73f' User entered 'None (1)'	System	13 Sep 2020 23:35:12
	System	13 Sep 2020 23:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e23f8ac3-d174-4d89-9e9e-1be22c90d73f' User entered '13 Sep 2020 18:35'	System	13 Sep 2020 23:35:12
	System	13 Sep 2020 23:35:12

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 7'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:10:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '669968c5-a451-4468-a993-4164d3969c71'	System	15 Sep 2020 01:10:57
User entered 'None (1)'	System	15 Sep 2020 01:10:57

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:10:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '669968c5-a451-4468-a993-4164d3969c71' User entered 'No (N)'	System	15 Sep 2020 01:10:57
	System	15 Sep 2020 01:10:57

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:10:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '669968c5-a451-4468-a993-4164d3969c71' User entered 'No (N)'	System	15 Sep 2020 01:10:57
	System	15 Sep 2020 01:10:57

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:10:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '669968c5-a451-4468-a993-4164d3969c71'	System	15 Sep 2020 01:10:57
User entered 'None (1)'	System	15 Sep 2020 01:10:57

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:10:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '669968c5-a451-4468-a993-4164d3969c71' User entered '14 Sep 2020 20:10'	System	15 Sep 2020 01:10:57
	System	15 Sep 2020 01:10:57

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980' User entered 'None (0)'	System	08 Sep 2020 21:52:07
	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980' User entered 'None (0)'	System	08 Sep 2020 21:52:07
	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980' User entered 'None (0)'	System	08 Sep 2020 21:52:07
	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980' User entered 'None (0)'	System	08 Sep 2020 21:52:07
	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980' User entered 'None (0)'	System	08 Sep 2020 21:52:07
	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:51:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980'	System	08 Sep 2020 21:52:07
User entered 'None (0)'	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:52:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980' User entered 'No (N)'	System	08 Sep 2020 21:52:07
	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T16:52:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '71b6bf16-5dc3-4606-8ba9-77fd09c1b980' User entered '08 Sep 2020 16:52'	System	08 Sep 2020 21:52:07
	System	08 Sep 2020 21:52:07

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 16:40'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 19:10'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered 'None (0)'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:03:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered 'None (0)'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:04:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered 'None (0)'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:04:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered 'None (0)'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:04:04', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered 'None (0)'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:04:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered 'None (0)'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:04:09', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered 'No (N)'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-08T21:04:12', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dd8ee6c2-623d-4809-8315-f3dbb6ecc9ea' User entered '08 Sep 2020 21:04'	System	09 Sep 2020 02:04:14
	System	09 Sep 2020 02:04:14

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Sep 2020 20:05'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 2'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:09:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered 'None (0)'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:10:30', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered 'None (0)'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:10:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered 'None (0)'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:10:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered 'None (0)'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:10:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered 'None (0)'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:10:40', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered 'None (0)'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:10:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered 'No (N)'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-09T19:10:45', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '826a33cf-5419-4aa4-99fd-1af15120fed5' User entered '09 Sep 2020 19:10'	System	10 Sep 2020 00:10:48
	System	10 Sep 2020 00:10:48

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 3'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:36', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04' User entered 'None (0)'	System	11 Sep 2020 00:02:53
	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04' User entered 'None (0)'	System	11 Sep 2020 00:02:53
	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04' User entered 'None (0)'	System	11 Sep 2020 00:02:53
	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:40', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04' User entered 'None (0)'	System	11 Sep 2020 00:02:53
	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04' User entered 'None (0)'	System	11 Sep 2020 00:02:53
	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04' User entered 'None (0)'	System	11 Sep 2020 00:02:53
	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04'	System	11 Sep 2020 00:02:53
User entered 'No (N)'	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-10T19:02:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5bc8cb1d-89ec-4e1c-9d37-e8605753ce04' User entered '10 Sep 2020 19:02'	System	11 Sep 2020 00:02:53
	System	11 Sep 2020 00:02:53

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 4'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b' User entered 'None (0)'	System	12 Sep 2020 04:35:40
	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:26', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b' User entered 'None (0)'	System	12 Sep 2020 04:35:40
	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b' User entered 'None (0)'	System	12 Sep 2020 04:35:40
	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b' User entered 'None (0)'	System	12 Sep 2020 04:35:40
	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:30', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b' User entered 'None (0)'	System	12 Sep 2020 04:35:40
	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:31', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b' User entered 'None (0)'	System	12 Sep 2020 04:35:40
	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b'	System	12 Sep 2020 04:35:40
User entered 'No (N)'	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-11T23:35:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3f298716-f83f-4948-8ebf-d455907f563b'	System	12 Sep 2020 04:35:40
User entered '11 Sep 2020 23:35'	System	12 Sep 2020 04:35:40

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 5'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:35:59', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered 'None (0)'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:36:01', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered 'None (0)'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:36:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered 'None (0)'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:36:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered 'None (0)'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:36:04', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered 'None (0)'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:36:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered 'None (0)'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:36:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered 'No (N)'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-12T19:36:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1af99162-69d9-4195-838e-1e51a50bf9a1' User entered '12 Sep 2020 19:36'	System	13 Sep 2020 00:36:15
	System	13 Sep 2020 00:36:15

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 6'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered 'None (0)'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered 'None (0)'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered 'None (0)'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered 'None (0)'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered 'None (0)'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered 'None (0)'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered 'No (N)'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-13T18:35:31', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f18848e-0879-417a-981f-723047fd0313' User entered '13 Sep 2020 18:35'	System	13 Sep 2020 23:35:35
	System	13 Sep 2020 23:35:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 7'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered 'None (0)'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:04', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered 'None (0)'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered 'None (0)'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered 'None (0)'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:07', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered 'None (0)'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered 'None (0)'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered 'No (N)'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-09-14T20:11:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9bd0f9fb-a774-42e5-bbee-37fa924a362e' User entered '14 Sep 2020 20:11'	System	15 Sep 2020 01:11:21
	System	15 Sep 2020 01:11:21

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:24:35

US3312551

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:58

US3312551

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '15 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:58

US3312551

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:07:58

US3312551

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4)	29 Sep 2020 20:07:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:01

US3312551

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'I'	System	29 Sep 2020 20:08:01

US3312551

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:20

US3312551

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '22 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:20

US3312551

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:08:20

US3312551

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4)	29 Sep 2020 20:08:20
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:08:23

US3312551

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:04:00
User entered 'I'	System	29 Sep 2020 20:08:23

US3312551

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:47
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:47

US3312551

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:47
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:47

US3312551

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:47
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:47

US3312551

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:47
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4)	29 Sep 2020 20:08:47
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:47
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:50

US3312551

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:47
User entered 'I'	System	29 Sep 2020 20:08:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:01:36

US3312551

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:01:36

US3312551

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:01:36

US3312551

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'VISIT2'	System	08 Oct 2020 15:01:36

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '08:27'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered '8 Oct 2020 08:27'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '85'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'bpm'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'breaths/min'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '114'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'mmHg'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '75'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'mmHg'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '10:29'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered '8 Oct 2020 10:29'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '77'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'bpm'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'breaths/min'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '118'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'mmHg'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '81'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'mmHg'	System	09 Oct 2020 20:34:10

US3312551

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:27

US3312551

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:27

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered empty.	System	09 Oct 2020 20:34:50

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:28
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Heather Barker (b) (4)	21 Oct 2020 18:40:40
' answered with 'updated' (Site from DM).	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Heather Barker (b) (4)	21 Oct 2020 18:40:31
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	14 Oct 2020 17:46:15
' (Site from DM).		
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '09:58'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered '08 Oct 2020 09:58'	System	21 Oct 2020 18:40:31
User entered '8 Oct 2020 09:58'	System	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'ONCE'	System	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:20:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 15:02:26

US3312551

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:12

US3312551

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:12

US3312551

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '09:20'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:12

US3312551

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered '8 Oct 2020 09:20'	System	09 Oct 2020 20:35:12

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '09:09'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User entered '8 Oct 2020 09:09'	System	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User entered empty.	System	09 Oct 2020 20:35:33

US3312551

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:02:34

US3312551

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:44
User entered 'I'	System	08 Oct 2020 15:02:34

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a97ea214-e486-47e4-979e-ef46004100cb' User entered 'Yes (Y)'	System	08 Oct 2020 15:33:37
	System	08 Oct 2020 15:33:37

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a97ea214-e486-47e4-979e-ef46004100cb' User entered '98.7'	System	08 Oct 2020 15:33:37
	System	08 Oct 2020 15:33:37

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:31', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a97ea214-e486-47e4-979e-ef46004100cb' User entered 'No (N)'	System	08 Oct 2020 15:33:37
	System	08 Oct 2020 15:33:37

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a97ea214-e486-47e4-979e-ef46004100cb' User entered '08 Oct 2020 10:33'	System	08 Oct 2020 15:33:37
	System	08 Oct 2020 15:33:37

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Oct 2020 10:18'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Oct 2020 12:48'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '969c2e19-8f9a-4c78-a806-9aac3cc310ae' User entered 'Yes (Y)'	System	09 Oct 2020 01:15:18
	System	09 Oct 2020 01:15:18

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:07', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '969c2e19-8f9a-4c78-a806-9aac3cc310ae' User entered '100.1'	System	09 Oct 2020 01:15:18
	System	09 Oct 2020 01:15:18

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:09', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '969c2e19-8f9a-4c78-a806-9aac3cc310ae' User entered 'No (N)'	System	09 Oct 2020 01:15:18
	System	09 Oct 2020 01:15:18

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '969c2e19-8f9a-4c78-a806-9aac3cc310ae'	System	09 Oct 2020 01:15:18
User entered '08 Oct 2020 20:15'	System	09 Oct 2020 01:15:18

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Oct 2020 13:43'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 2'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:35:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '85c3cac4-7a51-4fdb-b0be-0db3c50309eb' User entered 'Yes (Y)'	System	10 Oct 2020 02:36:07
	System	10 Oct 2020 02:36:07

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:35:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '85c3cac4-7a51-4fdb-b0be-0db3c50309eb' User entered '102.0'	System	10 Oct 2020 02:36:07
	System	10 Oct 2020 02:36:07

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:35:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '85c3cac4-7a51-4fdb-b0be-0db3c50309eb' User entered 'Yes (Y)'	System	10 Oct 2020 02:36:07
	System	10 Oct 2020 02:36:07

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 08:52:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:35:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '85c3cac4-7a51-4fdb-b0be-0db3c50309eb' User entered '1'	Karol Moore (b) (4) (b) (4)	27 Oct 2020 16:31:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Oct 2020 02:36:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:35:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '85c3cac4-7a51-4fdb-b0be-0db3c50309eb' User entered '1'	System	10 Oct 2020 02:36:07
User entered '1'	System	10 Oct 2020 02:36:07

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:35:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '85c3cac4-7a51-4fdb-b0be-0db3c50309eb' User entered '0'	System	10 Oct 2020 02:36:07
	System	10 Oct 2020 02:36:07

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:36:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '85c3cac4-7a51-4fdb-b0be-0db3c50309eb' User entered '09 Oct 2020 21:36'	System	10 Oct 2020 02:36:07
	System	10 Oct 2020 02:36:07

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 3'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4b227954-a46f-435f-b24b-ab5abd7b9c4b' User entered 'Yes (Y)'	System	11 Oct 2020 03:02:24
	System	11 Oct 2020 03:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:12', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4b227954-a46f-435f-b24b-ab5abd7b9c4b' User entered '97.8'	System	11 Oct 2020 03:02:24
	System	11 Oct 2020 03:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4b227954-a46f-435f-b24b-ab5abd7b9c4b'	System	11 Oct 2020 03:02:24
User entered 'No (N)'	System	11 Oct 2020 03:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4b227954-a46f-435f-b24b-ab5abd7b9c4b' User entered '10 Oct 2020 22:02'	System	11 Oct 2020 03:02:24
	System	11 Oct 2020 03:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 4'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:04', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '01bac106-df10-492b-ba3d-78db55f4c03b' User entered 'Yes (Y)'	System	11 Oct 2020 23:51:27
	System	11 Oct 2020 23:51:27

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '01bac106-df10-492b-ba3d-78db55f4c03b' User entered '98.8'	System	11 Oct 2020 23:51:27
	System	11 Oct 2020 23:51:27

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '01bac106-df10-492b-ba3d-78db55f4c03b'	System	11 Oct 2020 23:51:27
User entered 'No (N)'	System	11 Oct 2020 23:51:27

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '01bac106-df10-492b-ba3d-78db55f4c03b' User entered '11 Oct 2020 18:51'	System	11 Oct 2020 23:51:27
	System	11 Oct 2020 23:51:27

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 5'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:28:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e781fbf6-121e-4c0a-8214-4366f748bbbc'	System	13 Oct 2020 00:28:38
User entered 'Yes (Y)'	System	13 Oct 2020 00:28:38

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:28:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e781fbf6-121e-4c0a-8214-4366f748bbbc' User entered '98.1'	System	13 Oct 2020 00:28:38
	System	13 Oct 2020 00:28:38

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:28:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e781fbf6-121e-4c0a-8214-4366f748bbbc'	System	13 Oct 2020 00:28:38
User entered 'No (N)'	System	13 Oct 2020 00:28:38

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:28:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e781fbf6-121e-4c0a-8214-4366f748bbbc' User entered '12 Oct 2020 19:28'	System	13 Oct 2020 00:28:38
	System	13 Oct 2020 00:28:38

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 6'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:32:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3113bef4-9a68-43bc-a906-7df0b872f5ef' User entered 'Yes (Y)'	System	14 Oct 2020 02:32:51
	System	14 Oct 2020 02:32:51

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:32:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3113bef4-9a68-43bc-a906-7df0b872f5ef' User entered '97.0'	System	14 Oct 2020 02:32:51
	System	14 Oct 2020 02:32:51

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:32:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3113bef4-9a68-43bc-a906-7df0b872f5ef'	System	14 Oct 2020 02:32:51
User entered 'No (N)'	System	14 Oct 2020 02:32:51

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:32:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3113bef4-9a68-43bc-a906-7df0b872f5ef' User entered '13 Oct 2020 21:32'	System	14 Oct 2020 02:32:51
	System	14 Oct 2020 02:32:51

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 7'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '80a9047f-0175-440c-91da-5b6a646c3163' User entered 'Yes (Y)'	System	15 Oct 2020 01:58:24
	System	15 Oct 2020 01:58:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '80a9047f-0175-440c-91da-5b6a646c3163' User entered '98.5'	System	15 Oct 2020 01:58:24
	System	15 Oct 2020 01:58:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '80a9047f-0175-440c-91da-5b6a646c3163'	System	15 Oct 2020 01:58:24
User entered 'No (N)'	System	15 Oct 2020 01:58:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '80a9047f-0175-440c-91da-5b6a646c3163' User entered '14 Oct 2020 20:58'	System	15 Oct 2020 01:58:24
	System	15 Oct 2020 01:58:24

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '09600b4e-1e44-46b4-8725-82fddc4d86c5'	System	08 Oct 2020 15:33:57
User entered 'None (1)'	System	08 Oct 2020 15:33:57

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '09600b4e-1e44-46b4-8725-82fddc4d86c5' User entered 'No (N)'	System	08 Oct 2020 15:33:57
	System	08 Oct 2020 15:33:57

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:45', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '09600b4e-1e44-46b4-8725-82fddc4d86c5' User entered 'No (N)'	System	08 Oct 2020 15:33:57
	System	08 Oct 2020 15:33:57

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '09600b4e-1e44-46b4-8725-82fddc4d86c5'	System	08 Oct 2020 15:33:57
User entered 'None (1)'	System	08 Oct 2020 15:33:57

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '09600b4e-1e44-46b4-8725-82fddc4d86c5' User entered '08 Oct 2020 10:33'	System	08 Oct 2020 15:33:57
	System	08 Oct 2020 15:33:57

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '08 Oct 2020 10:18'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '08 Oct 2020 12:48'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Query 'Per DM CLR: Per Diary Dose 2 Day 1 (at home), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' canceled (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 19:15:09
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1 (at home), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:15:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1fc6779c-1297-4e70-b793-6e0892f07a90'	System	09 Oct 2020 01:15:50
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	09 Oct 2020 01:15:50

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:40', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1fc6779c-1297-4e70-b793-6e0892f07a90' User entered 'No (N)'	System	09 Oct 2020 01:15:50
	System	09 Oct 2020 01:15:50

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1fc6779c-1297-4e70-b793-6e0892f07a90'	System	09 Oct 2020 01:15:50
User entered 'No (N)'	System	09 Oct 2020 01:15:50

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1fc6779c-1297-4e70-b793-6e0892f07a90'	System	09 Oct 2020 01:15:50
User entered 'None (1)'	System	09 Oct 2020 01:15:50

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1fc6779c-1297-4e70-b793-6e0892f07a90'	System	09 Oct 2020 01:15:50
User entered '08 Oct 2020 20:15'	System	09 Oct 2020 01:15:50

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '08 Oct 2020 13:43'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 2'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:44:17', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bd48f8a4-a153-430f-ab50-52aa1d228b6d'	System	10 Oct 2020 02:44:32
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 02:44:32

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:44:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bd48f8a4-a153-430f-ab50-52aa1d228b6d' User entered 'No (N)'	System	10 Oct 2020 02:44:32
	System	10 Oct 2020 02:44:32

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:44:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bd48f8a4-a153-430f-ab50-52aa1d228b6d' User entered 'No (N)'	System	10 Oct 2020 02:44:32
	System	10 Oct 2020 02:44:32

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:44:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bd48f8a4-a153-430f-ab50-52aa1d228b6d' User entered 'None (1)'	System	10 Oct 2020 02:44:32
	System	10 Oct 2020 02:44:32

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:44:30', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bd48f8a4-a153-430f-ab50-52aa1d228b6d' User entered '09 Oct 2020 21:44'	System	10 Oct 2020 02:44:32
	System	10 Oct 2020 02:44:32

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 3'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a0325756-b216-4c0d-92df-8f7b5da8b8cd'	System	11 Oct 2020 03:02:44
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 03:02:44

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a0325756-b216-4c0d-92df-8f7b5da8b8cd' User entered 'No (N)'	System	11 Oct 2020 03:02:44
	System	11 Oct 2020 03:02:44

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a0325756-b216-4c0d-92df-8f7b5da8b8cd' User entered 'No (N)'	System	11 Oct 2020 03:02:44
	System	11 Oct 2020 03:02:44

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a0325756-b216-4c0d-92df-8f7b5da8b8cd'	System	11 Oct 2020 03:02:44
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 03:02:44

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a0325756-b216-4c0d-92df-8f7b5da8b8cd' User entered '10 Oct 2020 22:02'	System	11 Oct 2020 03:02:44
	System	11 Oct 2020 03:02:44

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 4'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62f43c29-43d6-479c-8cad-28380c041c2c' User entered 'None (1)'	System	11 Oct 2020 23:51:55
	System	11 Oct 2020 23:51:55

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62f43c29-43d6-479c-8cad-28380c041c2c' User entered 'No (N)'	System	11 Oct 2020 23:51:55
	System	11 Oct 2020 23:51:55

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:36', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62f43c29-43d6-479c-8cad-28380c041c2c' User entered 'No (N)'	System	11 Oct 2020 23:51:55
	System	11 Oct 2020 23:51:55

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62f43c29-43d6-479c-8cad-28380c041c2c'	System	11 Oct 2020 23:51:55
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 23:51:55

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:52', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62f43c29-43d6-479c-8cad-28380c041c2c' User entered '11 Oct 2020 18:51'	System	11 Oct 2020 23:51:55
	System	11 Oct 2020 23:51:55

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 5'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:28:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0c775623-e91f-48f8-9c29-d55f93f61367'	System	13 Oct 2020 00:29:07
User entered 'None (1)'	System	13 Oct 2020 00:29:07

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:28:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0c775623-e91f-48f8-9c29-d55f93f61367'	System	13 Oct 2020 00:29:07
User entered 'No (N)'	System	13 Oct 2020 00:29:07

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:28:45', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0c775623-e91f-48f8-9c29-d55f93f61367' User entered 'No (N)'	System	13 Oct 2020 00:29:07
	System	13 Oct 2020 00:29:07

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0c775623-e91f-48f8-9c29-d55f93f61367'	System	13 Oct 2020 00:29:07
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 00:29:07

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0c775623-e91f-48f8-9c29-d55f93f61367' User entered '12 Oct 2020 19:29'	System	13 Oct 2020 00:29:07
	System	13 Oct 2020 00:29:07

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 6'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:32:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a9b8f42f-30af-432c-a3bc-d479a025854f'	System	14 Oct 2020 02:35:47
User entered 'None (1)'	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:32:55', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a9b8f42f-30af-432c-a3bc-d479a025854f' User entered 'No (N)'	System	14 Oct 2020 02:35:47
	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:32:57', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a9b8f42f-30af-432c-a3bc-d479a025854f' User entered 'No (N)'	System	14 Oct 2020 02:35:47
	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a9b8f42f-30af-432c-a3bc-d479a025854f' User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 02:35:47
	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a9b8f42f-30af-432c-a3bc-d479a025854f' User entered '13 Oct 2020 21:35'	System	14 Oct 2020 02:35:47
	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 7'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '58a7ee7e-26e8-491f-a464-5f719b18b70a' User entered 'None (1)'	System	15 Oct 2020 01:58:52
	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '58a7ee7e-26e8-491f-a464-5f719b18b70a' User entered 'No (N)'	System	15 Oct 2020 01:58:52
	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '58a7ee7e-26e8-491f-a464-5f719b18b70a' User entered 'No (N)'	System	15 Oct 2020 01:58:52
	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '58a7ee7e-26e8-491f-a464-5f719b18b70a'	System	15 Oct 2020 01:58:52
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:58:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '58a7ee7e-26e8-491f-a464-5f719b18b70a' User entered '14 Oct 2020 20:58'	System	15 Oct 2020 01:58:52
	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Mar 2021 19:15:12
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:53', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered 'None (0)'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered 'None (0)'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered 'None (0)'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:57', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered 'None (0)'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:33:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered 'None (0)'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:34:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered 'None (0)'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:34:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered 'No (N)'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T10:34:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9642aae9-faba-4f8e-87fe-3fbf74ddb293'	System	08 Oct 2020 15:34:09
User entered '08 Oct 2020 10:34'	System	08 Oct 2020 15:34:09

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '08 Oct 2020 10:18'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '08 Oct 2020 12:48'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5'	System	09 Oct 2020 01:16:18
User entered 'None (0)'	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5'	System	09 Oct 2020 01:16:18
User entered 'No interference with activity (1)'	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:15:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5' User entered 'None (0)'	System	09 Oct 2020 01:16:18
	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:16:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5' User entered 'None (0)'	System	09 Oct 2020 01:16:18
	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:16:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5'	System	09 Oct 2020 01:16:18
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:16:09', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5'	System	09 Oct 2020 01:16:18
User entered 'No interference with activity (1)'	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:16:12', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5'	System	09 Oct 2020 01:16:18
User entered 'No (N)'	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-08T20:16:14', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0bf4f8a1-69c3-4b9e-a889-0fa6bd2b45f5'	System	09 Oct 2020 01:16:18
User entered '08 Oct 2020 20:16'	System	09 Oct 2020 01:16:18

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '08 Oct 2020 13:43'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 2'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 13:59:55
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'CONFIRMED WITH SUBJECT. CORRECT AS ENTERED. SUBJECT SELECTED GRADE 2 SYMPTOM PER "SOME INTERFERENCE WITH ACTIVITY". NO CON MEDS TAKEN.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 19:21:52
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:10:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:44:53', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	10 Oct 2020 02:47:58

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:47:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered 'No interference with activity (1)'	System	10 Oct 2020 02:47:58

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:47:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered 'No interference with activity (1)'	System	10 Oct 2020 02:47:58

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:47:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered 'None (0)'	System	10 Oct 2020 02:47:58

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:47:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered 'None (0)'	System	10 Oct 2020 02:47:58

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:47:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered 'Some interference with activity not requiring medical attention (2)'	System	10 Oct 2020 02:47:58

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:47:53', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered 'No (N)'	System	10 Oct 2020 02:47:58

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-09T21:47:55', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb22e058-17a7-45c2-a8f2-d5bfa6132f13'	System	10 Oct 2020 02:47:58
User entered '09 Oct 2020 21:47'	System	10 Oct 2020 02:47:58

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 3'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered 'None (0)'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered 'None (0)'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered 'None (0)'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:52', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered 'None (0)'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered 'None (0)'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:02:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered 'None (0)'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:03:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered 'No (N)'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-10T22:03:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '21f0dd07-c940-491f-9159-6f40de89b028' User entered '10 Oct 2020 22:03'	System	11 Oct 2020 03:03:08
	System	11 Oct 2020 03:03:08

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 4'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered 'None (0)'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:57', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered 'None (0)'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:51:59', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered 'None (0)'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:52:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered 'None (0)'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:52:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered 'None (0)'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:52:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered 'None (0)'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:52:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered 'No (N)'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-11T18:52:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '62fd32a6-13a1-44e2-ba7f-d3eabb1b6809' User entered '11 Oct 2020 18:52'	System	11 Oct 2020 23:52:12
	System	11 Oct 2020 23:52:12

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 5'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed'	System	13 Oct 2020 00:29:22
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed' User entered 'None (0)'	System	13 Oct 2020 00:29:22
	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:12', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed' User entered 'None (0)'	System	13 Oct 2020 00:29:22
	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed' User entered 'None (0)'	System	13 Oct 2020 00:29:22
	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed' User entered 'None (0)'	System	13 Oct 2020 00:29:22
	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed' User entered 'None (0)'	System	13 Oct 2020 00:29:22
	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed' User entered 'No (N)'	System	13 Oct 2020 00:29:22
	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-12T19:29:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ef8689b1-2487-409d-9617-7ef865c1f5ed'	System	13 Oct 2020 00:29:22
User entered '12 Oct 2020 19:29'	System	13 Oct 2020 00:29:22

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 6'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7'	System	14 Oct 2020 02:36:05
User entered 'No interference with activity (1)'	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7' User entered 'None (0)'	System	14 Oct 2020 02:36:05
	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7' User entered 'None (0)'	System	14 Oct 2020 02:36:05
	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:52', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7' User entered 'None (0)'	System	14 Oct 2020 02:36:05
	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7' User entered 'None (0)'	System	14 Oct 2020 02:36:05
	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:55', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7' User entered 'None (0)'	System	14 Oct 2020 02:36:05
	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:35:59', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7' User entered 'No (N)'	System	14 Oct 2020 02:36:05
	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-13T21:36:01', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '027811e3-7fd7-4b81-9275-3c7756bbe4a7' User entered '13 Oct 2020 21:36'	System	14 Oct 2020 02:36:05
	System	14 Oct 2020 02:36:05

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
Data entry locked.	System	08 Oct 2020 15:02:26
User entered 'Day 7'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189' User entered 'None (0)'	System	15 Oct 2020 01:59:42
	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189' User entered 'None (0)'	System	15 Oct 2020 01:59:42
	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:26', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189' User entered 'None (0)'	System	15 Oct 2020 01:59:42
	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189' User entered 'None (0)'	System	15 Oct 2020 01:59:42
	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189' User entered 'None (0)'	System	15 Oct 2020 01:59:42
	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:30', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189' User entered 'None (0)'	System	15 Oct 2020 01:59:42
	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189' User entered 'No (N)'	System	15 Oct 2020 01:59:42
	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-14T20:59:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0e2a3597-f8b0-452e-8cd6-f964282bb189'	System	15 Oct 2020 01:59:42
User entered '14 Oct 2020 20:59'	System	15 Oct 2020 01:59:42

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 21:50:33
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 15:02:26

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	14 Oct 2020 02:35:47
User entered 'Day 8'	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-15T19:52:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '336e2f6a-fba3-4d42-9490-301d1c073bcf' User entered 'No (N)'	System	16 Oct 2020 00:52:41
	System	16 Oct 2020 00:52:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-15T19:52:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '336e2f6a-fba3-4d42-9490-301d1c073bcf' User entered '15 Oct 2020 19:52'	System	16 Oct 2020 00:52:41
	System	16 Oct 2020 00:52:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	15 Oct 2020 01:58:52
User entered 'Day 9'	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-16T21:31:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '83781483-0b13-4929-95c8-c59936de1d06'	System	17 Oct 2020 02:32:15
User entered 'No (N)'	System	17 Oct 2020 02:32:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-16T21:32:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '83781483-0b13-4929-95c8-c59936de1d06'	System	17 Oct 2020 02:32:15
User entered '16 Oct 2020 21:32'	System	17 Oct 2020 02:32:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	16 Oct 2020 00:52:50
User entered 'Day 10'	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-17T20:28:01', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6afac01f-e338-4950-b99c-1a14de491753'	System	18 Oct 2020 01:28:06
User entered 'No (N)'	System	18 Oct 2020 01:28:06

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-17T20:28:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6afac01f-e338-4950-b99c-1a14de491753' User entered '17 Oct 2020 20:28'	System	18 Oct 2020 01:28:06
	System	18 Oct 2020 01:28:06

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	17 Oct 2020 02:32:29
User entered 'Day 11'	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-18T18:43:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b592f5fa-e8bd-49cc-9ff7-5fe80e48f356'	System	18 Oct 2020 23:43:56
User entered 'No (N)'	System	18 Oct 2020 23:43:56

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-18T18:43:53', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b592f5fa-e8bd-49cc-9ff7-5fe80e48f356'	System	18 Oct 2020 23:43:56
User entered '18 Oct 2020 18:43'	System	18 Oct 2020 23:43:56

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	18 Oct 2020 01:28:12
User entered 'Day 12'	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-19T20:00:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c56ecb9b-d02b-452a-a7fb-412496282474' User entered 'No (N)'	System	20 Oct 2020 01:00:44
	System	20 Oct 2020 01:00:44

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-19T20:00:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c56ecb9b-d02b-452a-a7fb-412496282474' User entered '19 Oct 2020 20:00'	System	20 Oct 2020 01:00:44
	System	20 Oct 2020 01:00:44

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	18 Oct 2020 23:44:03
User entered 'Day 13'	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-20T20:00:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9ed4134e-e5f2-4f1a-bbd6-e4f3fe57da93' User entered 'No (N)'	System	21 Oct 2020 01:00:53
	System	21 Oct 2020 01:00:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-20T20:00:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9ed4134e-e5f2-4f1a-bbd6-e4f3fe57da93' User entered '20 Oct 2020 20:00'	System	21 Oct 2020 01:00:53
	System	21 Oct 2020 01:00:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	20 Oct 2020 01:00:52
User entered 'Day 14'	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-21T20:00:55', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c0337d16-9868-4740-8788-5190b95f4586'	System	22 Oct 2020 01:01:02
User entered 'No (N)'	System	22 Oct 2020 01:01:02

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-21T20:00:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c0337d16-9868-4740-8788-5190b95f4586'	System	22 Oct 2020 01:01:02
User entered '21 Oct 2020 20:00'	System	22 Oct 2020 01:01:02

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	21 Oct 2020 01:00:57
User entered 'Day 15'	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-22T20:00:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e7e90e79-7702-4872-b768-c480bbb5d95b' User entered 'No (N)'	System	23 Oct 2020 01:00:32
	System	23 Oct 2020 01:00:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-22T20:00:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e7e90e79-7702-4872-b768-c480bbb5d95b' User entered '22 Oct 2020 20:00'	System	23 Oct 2020 01:00:32
	System	23 Oct 2020 01:00:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	22 Oct 2020 01:01:17
User entered 'Day 16'	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-23T20:09:26', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3b5c222e-6d21-4a01-87e5-8b618a02624c' User entered 'No (N)'	System	24 Oct 2020 01:09:30
	System	24 Oct 2020 01:09:30

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-23T20:09:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3b5c222e-6d21-4a01-87e5-8b618a02624c' User entered '23 Oct 2020 20:09'	System	24 Oct 2020 01:09:30
	System	24 Oct 2020 01:09:30

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	23 Oct 2020 01:00:39
User entered 'Day 17'	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-24T20:10:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '719d3783-b5fa-409c-9490-efed8cc54ea4'	System	25 Oct 2020 01:10:21
User entered 'No (N)'	System	25 Oct 2020 01:10:21

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-24T20:10:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '719d3783-b5fa-409c-9490-efed8cc54ea4'	System	25 Oct 2020 01:10:21
User entered '24 Oct 2020 20:10'	System	25 Oct 2020 01:10:21

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	24 Oct 2020 01:09:40
User entered 'Day 18'	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-25T20:00:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ba1450af-1f63-4ae6-8559-74f9602c4db3'	System	26 Oct 2020 01:00:43
User entered 'No (N)'	System	26 Oct 2020 01:00:43

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-25T20:00:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ba1450af-1f63-4ae6-8559-74f9602c4db3' User entered '25 Oct 2020 20:00'	System	26 Oct 2020 01:00:43
	System	26 Oct 2020 01:00:43

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	25 Oct 2020 01:10:29
User entered 'Day 19'	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-26T20:09:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'be58da01-80d7-47ad-bc38-375995bbc472' User entered 'No (N)'	System	27 Oct 2020 01:09:21
	System	27 Oct 2020 01:09:21

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-26T20:09:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'be58da01-80d7-47ad-bc38-375995bbc472' User entered '26 Oct 2020 20:09'	System	27 Oct 2020 01:09:21
	System	27 Oct 2020 01:09:21

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	26 Oct 2020 01:00:49
User entered 'Day 20'	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-27T19:48:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '12b2f24b-9bf1-4662-844b-88a231466c1d' User entered 'No (N)'	System	28 Oct 2020 00:48:09
	System	28 Oct 2020 00:48:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-27T19:48:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '12b2f24b-9bf1-4662-844b-88a231466c1d' User entered '27 Oct 2020 19:48'	System	28 Oct 2020 00:48:09
	System	28 Oct 2020 00:48:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	27 Oct 2020 01:09:26
User entered 'Day 21'	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-28T20:00:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8e7d846a-c9f2-40e6-8106-40ab87895c5e' User entered 'No (N)'	System	29 Oct 2020 01:00:49
	System	29 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-28T20:00:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8e7d846a-c9f2-40e6-8106-40ab87895c5e' User entered '28 Oct 2020 20:00'	System	29 Oct 2020 01:00:49
	System	29 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	28 Oct 2020 00:48:15
User entered 'Day 22'	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-29T20:00:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1a72c7fd-8618-4456-9d88-dbf8a2dcfb0a' User entered 'No (N)'	System	30 Oct 2020 01:00:42
	System	30 Oct 2020 01:00:42

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-29T20:00:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1a72c7fd-8618-4456-9d88-dbf8a2dcfb0a' User entered '29 Oct 2020 20:00'	System	30 Oct 2020 01:00:42
	System	30 Oct 2020 01:00:42

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	29 Oct 2020 01:00:52
User entered 'Day 23'	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-30T19:57:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '32a6fa07-eeee-46a9-9e2e-e0e15e9407e2' User entered 'No (N)'	System	31 Oct 2020 00:57:40
	System	31 Oct 2020 00:57:40

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-30T19:57:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '32a6fa07-eeee-46a9-9e2e-e0e15e9407e2' User entered '30 Oct 2020 19:57'	System	31 Oct 2020 00:57:40
	System	31 Oct 2020 00:57:40

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	30 Oct 2020 01:01:08
User entered 'Day 24'	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-31T20:09:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '58b7ad3b-913c-482a-8708-da8550117fcf' User entered 'No (N)'	System	01 Nov 2020 01:09:41
	System	01 Nov 2020 01:09:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-31T20:09:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '58b7ad3b-913c-482a-8708-da8550117fcf' User entered '31 Oct 2020 20:09'	System	01 Nov 2020 01:09:41
	System	01 Nov 2020 01:09:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	31 Oct 2020 00:57:47
User entered 'Day 25'	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-01T20:21:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f0efb137-f68d-467c-aac8-e5817e16f664'	System	02 Nov 2020 02:21:10
User entered 'No (N)'	System	02 Nov 2020 02:21:10

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-01T20:21:08', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f0efb137-f68d-467c-aac8-e5817e16f664'	System	02 Nov 2020 02:21:10
User entered '01 Nov 2020 20:21'	System	02 Nov 2020 02:21:10

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Nov 2020 12:00'	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Nov 2020 11:59'	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	01 Nov 2020 01:09:48
User entered 'Day 26'	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-02T20:03:12', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c0828302-9542-4c40-8fc7-b5aba9edeab1' User entered 'No (N)'	System	03 Nov 2020 02:03:27
	System	03 Nov 2020 02:03:27

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-02T20:03:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c0828302-9542-4c40-8fc7-b5aba9edeab1' User entered '02 Nov 2020 20:03'	System	03 Nov 2020 02:03:27
	System	03 Nov 2020 02:03:27

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	02 Nov 2020 02:21:15
User entered 'Day 27'	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T05:59:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '87f30447-a623-440e-afea-1e8560263aa7' User entered 'No (N)'	System	04 Nov 2020 11:59:22
	System	04 Nov 2020 11:59:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T05:59:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '87f30447-a623-440e-afea-1e8560263aa7' User entered '04 Nov 2020 05:59'	System	04 Nov 2020 11:59:22
	System	04 Nov 2020 11:59:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	03 Nov 2020 02:03:32
User entered 'Day 28'	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T21:25:52', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9c8d07d4-971b-4ca5-9e1c-f08a10a48a13' User entered 'No (N)'	System	05 Nov 2020 03:25:58
	System	05 Nov 2020 03:25:58

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T21:25:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9c8d07d4-971b-4ca5-9e1c-f08a10a48a13' User entered '04 Nov 2020 21:25'	System	05 Nov 2020 03:25:58
	System	05 Nov 2020 03:25:58

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Nov 2020 12:00'	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Nov 2020 11:59'	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	04 Nov 2020 11:59:29
User entered 'Day 29'	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-05T22:06:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f14d13ea-d6dd-431e-89c0-4c018a5cabad' User entered 'No (N)'	System	06 Nov 2020 04:06:24
	System	06 Nov 2020 04:06:24

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-05T22:06:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f14d13ea-d6dd-431e-89c0-4c018a5cabad' User entered '05 Nov 2020 22:06'	System	06 Nov 2020 04:06:24
	System	06 Nov 2020 04:06:24

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	05 Nov 2020 03:26:01
User entered 'Day 30'	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-06T20:00:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5e9f9dd4-a609-4fad-97ca-b87c006a08d4' User entered 'No (N)'	System	07 Nov 2020 02:00:37
	System	07 Nov 2020 02:00:37

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-06T20:00:34', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5e9f9dd4-a609-4fad-97ca-b87c006a08d4'	System	07 Nov 2020 02:00:37
User entered '06 Nov 2020 20:00'	System	07 Nov 2020 02:00:37

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	06 Nov 2020 04:06:32
User entered 'Day 31'	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-07T12:00:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b548716d-114a-4203-88e0-b3f1b33c49b9' User entered 'No (N)'	System	07 Nov 2020 18:00:28
	System	07 Nov 2020 18:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-07T12:00:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b548716d-114a-4203-88e0-b3f1b33c49b9' User entered '07 Nov 2020 12:00'	System	07 Nov 2020 18:00:28
	System	07 Nov 2020 18:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	07 Nov 2020 18:00:48
User entered 'Day 32'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-08T12:05:36', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c0d57d2c-a431-4a2f-aaa2-435126c4ecaf' User entered 'No (N)'	System	08 Nov 2020 18:05:40
	System	08 Nov 2020 18:05:40

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-08T12:05:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c0d57d2c-a431-4a2f-aaa2-435126c4ecaf' User entered '08 Nov 2020 12:05'	System	08 Nov 2020 18:05:40
	System	08 Nov 2020 18:05:40

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	07 Nov 2020 18:00:48
User entered 'Day 33'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-09T19:12:38', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e891b298-6f53-47a2-9bf6-4bc1cae93729'	System	10 Nov 2020 01:12:49
User entered 'No (N)'	System	10 Nov 2020 01:12:49

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-09T19:12:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e891b298-6f53-47a2-9bf6-4bc1cae93729' User entered '09 Nov 2020 19:12'	System	10 Nov 2020 01:12:49
	System	10 Nov 2020 01:12:49

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Nov 2020 18:05:54
User entered 'Day 34'	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-10T19:59:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'db9bff5b-a174-4977-a409-a359b0d1ae69' User entered 'No (N)'	System	11 Nov 2020 01:59:59
	System	11 Nov 2020 01:59:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-10T19:59:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'db9bff5b-a174-4977-a409-a359b0d1ae69' User entered '10 Nov 2020 19:59'	System	11 Nov 2020 01:59:59
	System	11 Nov 2020 01:59:59

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Nov 2020 12:00'	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Nov 2020 11:59'	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	10 Nov 2020 01:12:51
User entered 'Day 35'	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-11T21:12:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8d206ace-1d95-4034-85cb-fd50743bfe28' User entered 'No (N)'	System	12 Nov 2020 03:13:04
	System	12 Nov 2020 03:13:04

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-11T21:13:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8d206ace-1d95-4034-85cb-fd50743bfe28' User entered '11 Nov 2020 21:13'	System	12 Nov 2020 03:13:04
	System	12 Nov 2020 03:13:04

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	11 Nov 2020 02:00:17
User entered 'Day 36'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-12T20:00:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b717206a-647e-4cff-863f-6ebf6e0378c6' User entered 'No (N)'	System	13 Nov 2020 02:00:45
	System	13 Nov 2020 02:00:45

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-12T20:00:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b717206a-647e-4cff-863f-6ebf6e0378c6' User entered '12 Nov 2020 20:00'	System	13 Nov 2020 02:00:45
	System	13 Nov 2020 02:00:45

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	12 Nov 2020 03:13:09
User entered 'Day 37'	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-13T20:02:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bd2aecbd-c45d-4813-85ed-27a471d5a979' User entered 'No (N)'	System	14 Nov 2020 02:02:09
	System	14 Nov 2020 02:02:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-13T20:02:07', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bd2aecbd-c45d-4813-85ed-27a471d5a979' User entered '13 Nov 2020 20:02'	System	14 Nov 2020 02:02:09
	System	14 Nov 2020 02:02:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	13 Nov 2020 02:00:52
User entered 'Day 38'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-14T22:35:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f86f824d-1222-4a5d-90ab-3b1670c826e6'	System	15 Nov 2020 04:35:53
User entered 'No (N)'	System	15 Nov 2020 04:35:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-14T22:35:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f86f824d-1222-4a5d-90ab-3b1670c826e6'	System	15 Nov 2020 04:35:53
User entered '14 Nov 2020 22:35'	System	15 Nov 2020 04:35:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Nov 2020 12:00'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Nov 2020 11:59'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	14 Nov 2020 02:02:24
User entered 'Day 39'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-15T20:00:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9523b496-073c-4989-8876-7c708e75d265'	System	16 Nov 2020 02:00:16
User entered 'No (N)'	System	16 Nov 2020 02:00:16

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-15T20:00:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9523b496-073c-4989-8876-7c708e75d265'	System	16 Nov 2020 02:00:16
User entered '15 Nov 2020 20:00'	System	16 Nov 2020 02:00:16

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	15 Nov 2020 04:36:08
User entered 'Day 40'	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-16T20:00:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0710da50-e960-4fa3-9882-8402fd57532c' User entered 'No (N)'	System	17 Nov 2020 02:00:53
	System	17 Nov 2020 02:00:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-16T20:00:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0710da50-e960-4fa3-9882-8402fd57532c' User entered '16 Nov 2020 20:00'	System	17 Nov 2020 02:00:53
	System	17 Nov 2020 02:00:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	16 Nov 2020 02:00:28
User entered 'Day 41'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-17T21:30:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4e51dd33-66ab-4188-a09d-50f98c1c1bcb' User entered 'No (N)'	System	18 Nov 2020 03:30:52
	System	18 Nov 2020 03:30:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-17T21:30:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4e51dd33-66ab-4188-a09d-50f98c1c1bcb' User entered '17 Nov 2020 21:30'	System	18 Nov 2020 03:30:52
	System	18 Nov 2020 03:30:52

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	17 Nov 2020 02:01:05
User entered 'Day 42'	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-18T20:01:40', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '45b85917-ef0d-4b95-a078-2bcd1a818db9' User entered 'No (N)'	System	19 Nov 2020 02:01:45
	System	19 Nov 2020 02:01:45

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-18T20:01:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '45b85917-ef0d-4b95-a078-2bcd1a818db9' User entered '18 Nov 2020 20:01'	System	19 Nov 2020 02:01:45
	System	19 Nov 2020 02:01:45

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	18 Nov 2020 03:31:48
User entered 'Day 43'	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-19T20:00:34', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '7ebe7b90-5e39-44d4-9d85-59d54dcd1d7c' User entered 'Yes (Y)'	System	20 Nov 2020 02:00:42
	System	20 Nov 2020 02:00:42

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-19T20:00:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '7ebe7b90-5e39-44d4-9d85-59d54dcd1d7c' User entered '19 Nov 2020 20:00'	System	20 Nov 2020 02:00:42
	System	20 Nov 2020 02:00:42

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	19 Nov 2020 02:01:51
User entered 'Day 44'	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-20T20:00:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '047d286e-f710-432a-ab7a-b17638d2bdac' User entered 'No (N)'	System	21 Nov 2020 02:00:21
	System	21 Nov 2020 02:00:21

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-20T20:00:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '047d286e-f710-432a-ab7a-b17638d2bdac' User entered '20 Nov 2020 20:00'	System	21 Nov 2020 02:00:21
	System	21 Nov 2020 02:00:21

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	20 Nov 2020 02:00:55
User entered 'Day 45'	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-21T20:02:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a1405dd6-fe96-4755-9ff6-b068f08ce657'	System	22 Nov 2020 02:02:23
User entered 'No (N)'	System	22 Nov 2020 02:02:23

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-21T20:02:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a1405dd6-fe96-4755-9ff6-b068f08ce657'	System	22 Nov 2020 02:02:23
User entered '21 Nov 2020 20:02'	System	22 Nov 2020 02:02:23

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	21 Nov 2020 02:00:34
User entered 'Day 46'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-22T20:00:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c523e207-41a8-43fc-aa31-49612f2696cb' User entered 'No (N)'	System	23 Nov 2020 02:00:32
	System	23 Nov 2020 02:00:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-22T20:00:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c523e207-41a8-43fc-aa31-49612f2696cb' User entered '22 Nov 2020 20:00'	System	23 Nov 2020 02:00:32
	System	23 Nov 2020 02:00:32

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	22 Nov 2020 02:03:01
User entered 'Day 47'	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-23T21:39:42', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b8050e97-bb8d-4c96-87a9-e04fc18e87fc' User entered 'No (N)'	System	24 Nov 2020 03:39:47
	System	24 Nov 2020 03:39:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-23T21:39:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b8050e97-bb8d-4c96-87a9-e04fc18e87fc' User entered '23 Nov 2020 21:39'	System	24 Nov 2020 03:39:47
	System	24 Nov 2020 03:39:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	23 Nov 2020 02:00:38
User entered 'Day 48'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-24T21:48:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5f4adfcc-e3e9-413a-8ad7-60c9f975096d' User entered 'No (N)'	System	25 Nov 2020 03:48:17
	System	25 Nov 2020 03:48:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-24T21:48:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5f4adfcc-e3e9-413a-8ad7-60c9f975096d' User entered '24 Nov 2020 21:48'	System	25 Nov 2020 03:48:17
	System	25 Nov 2020 03:48:17

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	24 Nov 2020 03:39:53
User entered 'Day 49'	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-25T20:12:14', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bdb84f88-9950-4ff8-acec-0ee73f56b09f' User entered 'No (N)'	System	26 Nov 2020 02:12:22
	System	26 Nov 2020 02:12:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-25T20:12:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bdb84f88-9950-4ff8-acec-0ee73f56b09f' User entered '25 Nov 2020 20:12'	System	26 Nov 2020 02:12:22
	System	26 Nov 2020 02:12:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Nov 2020 12:00'	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Nov 2020 11:59'	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	25 Nov 2020 03:48:22
User entered 'Day 50'	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-26T21:26:04', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '28ead625-6bb7-4dfe-8de4-0e38c88fcca7' User entered 'No (N)'	System	27 Nov 2020 03:26:14
	System	27 Nov 2020 03:26:14

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-26T21:26:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '28ead625-6bb7-4dfe-8de4-0e38c88fcca7' User entered '26 Nov 2020 21:26'	System	27 Nov 2020 03:26:14
	System	27 Nov 2020 03:26:14

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Nov 2020 12:00'	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Nov 2020 11:59'	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	26 Nov 2020 02:12:33
User entered 'Day 51'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-28T09:35:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1f880ef4-eaca-497f-8c42-c597e6dd8582' User entered 'No (N)'	System	28 Nov 2020 15:35:22
	System	28 Nov 2020 15:35:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-28T09:35:20', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1f880ef4-eaca-497f-8c42-c597e6dd8582' User entered '28 Nov 2020 09:35'	System	28 Nov 2020 15:35:22
	System	28 Nov 2020 15:35:22

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Nov 2020 12:00'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Nov 2020 11:59'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	27 Nov 2020 03:26:19
User entered 'Day 52'	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Nov 2020 12:00'	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Nov 2020 11:59'	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	28 Nov 2020 15:35:31
User entered 'Day 53'	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-29T12:00:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a3607a48-e787-4b22-a2a0-3c3409ef3fa8' User entered 'No (N)'	System	29 Nov 2020 18:00:38
	System	29 Nov 2020 18:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-29T12:00:34', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a3607a48-e787-4b22-a2a0-3c3409ef3fa8' User entered '29 Nov 2020 12:00'	System	29 Nov 2020 18:00:38
	System	29 Nov 2020 18:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Nov 2020 12:00'	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Nov 2020 11:59'	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	29 Nov 2020 18:00:41
User entered 'Day 54'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-30T20:01:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '38a8260a-2e1f-43c8-a71e-399ce2275813' User entered 'No (N)'	System	01 Dec 2020 02:01:43
	System	01 Dec 2020 02:01:43

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-30T20:01:40', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '38a8260a-2e1f-43c8-a71e-399ce2275813' User entered '30 Nov 2020 20:01'	System	01 Dec 2020 02:01:43
	System	01 Dec 2020 02:01:43

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Nov 2020 12:00'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Dec 2020 11:59'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	29 Nov 2020 18:00:41
User entered 'Day 55'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-01T20:00:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a1e599d6-1816-4786-8489-6167ec1ad94c' User entered 'No (N)'	System	02 Dec 2020 02:00:50
	System	02 Dec 2020 02:00:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-01T20:00:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a1e599d6-1816-4786-8489-6167ec1ad94c' User entered '01 Dec 2020 20:00'	System	02 Dec 2020 02:00:50
	System	02 Dec 2020 02:00:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Dec 2020 12:00'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Dec 2020 11:59'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	01 Dec 2020 02:01:54
User entered 'Day 56'	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T06:27:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'fbbc342d-039f-403a-8af5-ac6ff644561c' User entered 'No (N)'	System	03 Dec 2020 12:28:03
	System	03 Dec 2020 12:28:03

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T06:27:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'fbbc342d-039f-403a-8af5-ac6ff644561c' User entered '03 Dec 2020 06:27'	System	03 Dec 2020 12:28:03
	System	03 Dec 2020 12:28:03

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Dec 2020 12:00'	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Dec 2020 11:59'	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	02 Dec 2020 02:00:57
User entered 'Day 57'	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T12:00:45', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '20fe3314-6888-48f6-ae52-5ccf755c4852'	System	03 Dec 2020 18:00:53
User entered 'No (N)'	System	03 Dec 2020 18:00:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T12:00:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '20fe3314-6888-48f6-ae52-5ccf755c4852'	System	03 Dec 2020 18:00:53
User entered '03 Dec 2020 12:00'	System	03 Dec 2020 18:00:53

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Dec 2020 12:00'	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Dec 2020 11:59'	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	03 Dec 2020 12:28:09
User entered 'Day 58'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-04T21:20:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f5ff66c3-c9a2-4417-82a2-beb444917bfc' User entered 'Yes (Y)'	System	05 Dec 2020 03:20:24
	System	05 Dec 2020 03:20:24

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-04T21:20:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f5ff66c3-c9a2-4417-82a2-beb444917bfc' User entered '04 Dec 2020 21:20'	System	05 Dec 2020 03:20:24
	System	05 Dec 2020 03:20:24

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Dec 2020 12:00'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Dec 2020 11:59'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	03 Dec 2020 18:00:56
User entered 'Day 59'	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-05T20:16:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1fd2d72b-9fe6-419b-922d-d579328c2a29' User entered 'No (N)'	System	06 Dec 2020 02:16:47
	System	06 Dec 2020 02:16:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-05T20:16:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1fd2d72b-9fe6-419b-922d-d579328c2a29' User entered '05 Dec 2020 20:16'	System	06 Dec 2020 02:16:47
	System	06 Dec 2020 02:16:47

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Dec 2020 12:00'	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Dec 2020 11:59'	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	05 Dec 2020 03:20:30
User entered 'Day 60'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-06T20:00:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8ba47349-adf7-415d-b6d2-ada6bf95dfb7' User entered 'No (N)'	System	07 Dec 2020 02:00:27
	System	07 Dec 2020 02:00:27

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-06T20:00:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8ba47349-adf7-415d-b6d2-ada6bf95dfb7' User entered '06 Dec 2020 20:00'	System	07 Dec 2020 02:00:27
	System	07 Dec 2020 02:00:27

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Dec 2020 12:00'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Dec 2020 11:59'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	06 Dec 2020 02:16:50
User entered 'Day 61'	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-07T17:22:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8844fff4-4d0b-4b16-84fc-a715a9919548'	System	07 Dec 2020 23:22:56
User entered 'No (N)'	System	07 Dec 2020 23:22:56

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-07T17:22:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8844fff4-4d0b-4b16-84fc-a715a9919548'	System	07 Dec 2020 23:22:56
User entered '07 Dec 2020 17:22'	System	07 Dec 2020 23:22:56

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Dec 2020 12:00'	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Dec 2020 11:59'	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	07 Dec 2020 02:00:38
User entered 'Day 62'	System	07 Dec 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 11 Aug 2021 22:20:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-08T21:25:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb61b47f-6f54-42a2-be0b-c83b241e9e2e' User entered 'No (N)'	System	09 Dec 2020 03:26:01
	System	09 Dec 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 11 Aug 2021 22:20:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-08T21:25:59', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'cb61b47f-6f54-42a2-be0b-c83b241e9e2e' User entered '08 Dec 2020 21:25'	System	09 Dec 2020 03:26:01
	System	09 Dec 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Dec 2020 12:00'	System	07 Dec 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Dec 2020 11:59'	System	07 Dec 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	14 Oct 2020 02:35:47
User entered 'Day 8'	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-15T19:52:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '559fa8b4-bf7d-4a22-abbc-17abbe0fa3a7'	System	16 Oct 2020 00:52:50
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-15T19:52:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '559fa8b4-bf7d-4a22-abb0-17abbe0fa3a7' User entered '15 Oct 2020 19:52'	System	16 Oct 2020 00:52:50
	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 02:35:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	15 Oct 2020 01:58:52
User entered 'Day 9'	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-16T21:32:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '361cb7d1-dc78-41e4-a95f-b4bc1bf38b39'	System	17 Oct 2020 02:32:29
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-16T21:32:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '361cb7d1-dc78-41e4-a95f-b4bc1bf38b39' User entered '16 Oct 2020 21:32'	System	17 Oct 2020 02:32:29
	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 01:58:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	16 Oct 2020 00:52:50
User entered 'Day 10'	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-17T20:28:07', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'fe25e2bf-5cf5-4624-bbc3-2b4f477bfc1b'	System	18 Oct 2020 01:28:12
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-17T20:28:09', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'fe25e2bf-5cf5-4624-bbc3-2b4f477bfc1b' User entered '17 Oct 2020 20:28'	System	18 Oct 2020 01:28:12
	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 00:52:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	17 Oct 2020 02:32:29
User entered 'Day 11'	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-18T18:43:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd6d59402-4cb7-4b3f-88a4-8eef09aabbf8'	System	18 Oct 2020 23:44:03
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-18T18:44:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd6d59402-4cb7-4b3f-88a4-8eef09aabbf8' User entered '18 Oct 2020 18:44'	System	18 Oct 2020 23:44:03
	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 02:32:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	18 Oct 2020 01:28:12
User entered 'Day 12'	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-19T20:00:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2186276a-f9a2-4964-b8a5-f9914bc4e722'	System	20 Oct 2020 01:00:52
User entered 'Does not interfere with activity (2)'	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-19T20:00:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2186276a-f9a2-4964-b8a5-f9914bc4e722' User entered '19 Oct 2020 20:00'	System	20 Oct 2020 01:00:52
	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 01:28:12

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(13)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	18 Oct 2020 23:44:03
User entered 'Day 13'	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(13)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-20T20:00:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '12b22d30-cf48-40d6-831f-b560accd3a25'	System	21 Oct 2020 01:00:57
User entered 'Does not interfere with activity (2)'	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(13)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-20T20:00:55', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '12b22d30-cf48-40d6-831f-b560accd3a25' User entered '20 Oct 2020 20:00'	System	21 Oct 2020 01:00:57
	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(13)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(13)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 23:44:03

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(14)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	20 Oct 2020 01:00:52
User entered 'Day 14'	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(14)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-21T20:01:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '08be3b98-fa59-46fc-bab6-81e8f40b70f6'	System	22 Oct 2020 01:01:17
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(14)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-21T20:01:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '08be3b98-fa59-46fc-bab6-81e8f40b70f6' User entered '21 Oct 2020 20:01'	System	22 Oct 2020 01:01:17
	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(14)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(14)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(15)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	21 Oct 2020 01:00:57
User entered 'Day 15'	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(15)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-22T20:00:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8fa6edc1-5c51-4554-8550-56843e4a6be8'	System	23 Oct 2020 01:00:39
User entered 'Does not interfere with activity (2)'	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(15)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-22T20:00:34', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8fa6edc1-5c51-4554-8550-56843e4a6be8' User entered '22 Oct 2020 20:00'	System	23 Oct 2020 01:00:39
	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(15)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(15)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 01:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(16)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	22 Oct 2020 01:01:17
User entered 'Day 16'	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(16)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-23T20:09:34', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2d009da3-5279-4764-8a88-ea923c37067e'	System	24 Oct 2020 01:09:40
User entered 'Does not interfere with activity (2)'	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(16)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-23T20:09:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2d009da3-5279-4764-8a88-ea923c37067e' User entered '23 Oct 2020 20:09'	System	24 Oct 2020 01:09:40
	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(16)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(16)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:01:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(17)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	23 Oct 2020 01:00:39
User entered 'Day 17'	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(17)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-24T20:10:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '51524120-2e03-44f9-8d18-6f4cc817ca7f'	System	25 Oct 2020 01:10:29
User entered 'Does not interfere with activity (2)'	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(17)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-24T20:10:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '51524120-2e03-44f9-8d18-6f4cc817ca7f' User entered '24 Oct 2020 20:10'	System	25 Oct 2020 01:10:29
	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(17)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(17)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 01:00:39

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(18)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	24 Oct 2020 01:09:40
User entered 'Day 18'	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(18)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-25T20:00:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bc2ccee6-6479-45f2-bb79-53f08468c07b'	System	26 Oct 2020 01:00:49
User entered 'Does not interfere with activity (2)'	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(18)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-25T20:00:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'bc2ccee6-6479-45f2-bb79-53f08468c07b' User entered '25 Oct 2020 20:00'	System	26 Oct 2020 01:00:49
	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(18)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(18)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:09:40

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(19)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	25 Oct 2020 01:10:29
User entered 'Day 19'	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(19)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-26T20:09:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b23bb3af-646f-4976-965c-d67fde098ea3'	System	27 Oct 2020 01:09:26
User entered 'Does not interfere with activity (2)'	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(19)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-26T20:09:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b23bb3af-646f-4976-965c-d67fde098ea3' User entered '26 Oct 2020 20:09'	System	27 Oct 2020 01:09:26
	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(19)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(19)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 01:10:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(20)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	26 Oct 2020 01:00:49
User entered 'Day 20'	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(20)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-27T19:48:09', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '89463a9f-7b74-4f75-b33a-16a6c1b90a64'	System	28 Oct 2020 00:48:15
User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(20)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-27T19:48:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '89463a9f-7b74-4f75-b33a-16a6c1b90a64' User entered '27 Oct 2020 19:48'	System	28 Oct 2020 00:48:15
	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(20)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(20)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 01:00:49

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(21)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	27 Oct 2020 01:09:26
User entered 'Day 21'	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(21)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-28T20:00:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6a10874a-08e7-4b5c-92e8-6df8064a83fd'	System	29 Oct 2020 01:00:52
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(21)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-28T20:00:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6a10874a-08e7-4b5c-92e8-6df8064a83fd' User entered '28 Oct 2020 20:00'	System	29 Oct 2020 01:00:52
	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(21)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(21)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 01:09:26

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(22)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	28 Oct 2020 00:48:15
User entered 'Day 22'	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(22)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-29T20:01:01', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd701f21e-c9a9-4c2e-b18f-644aed14c030'	System	30 Oct 2020 01:01:08
User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(22)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-29T20:01:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd701f21e-c9a9-4c2e-b18f-644aed14c030' User entered '29 Oct 2020 20:01'	System	30 Oct 2020 01:01:08
	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(22)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(22)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 00:48:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(23)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	29 Oct 2020 01:00:52
User entered 'Day 23'	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(23)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-30T19:57:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9de5f2e9-32f9-4245-857d-8c35fe85384e'	System	31 Oct 2020 00:57:47
User entered 'Does not interfere with activity (2)'	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(23)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-30T19:57:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9de5f2e9-32f9-4245-857d-8c35fe85384e' User entered '30 Oct 2020 19:57'	System	31 Oct 2020 00:57:47
	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(23)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(23)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 01:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(24)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	30 Oct 2020 01:01:08
User entered 'Day 24'	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(24)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-31T20:09:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ea429b82-f680-42ac-bdd5-63a4f3e826f8'	System	01 Nov 2020 01:09:48
User entered 'Does not interfere with activity (2)'	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(24)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-10-31T20:09:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ea429b82-f680-42ac-bdd5-63a4f3e826f8' User entered '31 Oct 2020 20:09'	System	01 Nov 2020 01:09:48
	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(24)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(24)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 01:01:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(25)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	31 Oct 2020 00:57:47
User entered 'Day 25'	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(25)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-01T20:21:11', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'efcf3c61-85f9-4d93-a02a-6d42f2fec62f'	System	02 Nov 2020 02:21:15
User entered 'Does not interfere with activity (2)'	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(25)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-01T20:21:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'efcf3c61-85f9-4d93-a02a-6d42f2fec62f' User entered '01 Nov 2020 20:21'	System	02 Nov 2020 02:21:15
	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(25)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Nov 2020 12:00'	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(25)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Nov 2020 11:59'	System	31 Oct 2020 00:57:47

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(26)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	01 Nov 2020 01:09:48
User entered 'Day 26'	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(26)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-02T20:03:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '7ffddba4-6930-4501-987f-19a5be1c9f8b'	System	03 Nov 2020 02:03:32
User entered 'Does not interfere with activity (2)'	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(26)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-02T20:03:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '7ffddb4-6930-4501-987f-19a5be1c9f8b' User entered '02 Nov 2020 20:03'	System	03 Nov 2020 02:03:32
	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(26)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(26)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 01:09:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(27)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	02 Nov 2020 02:21:15
User entered 'Day 27'	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(27)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T05:59:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '43a6211f-21d9-4998-901d-d5d0c5f3b3c4'	System	04 Nov 2020 11:59:29
User entered 'Does not interfere with activity (2)'	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(27)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T05:59:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '43a6211f-21d9-4998-901d-d5d0c5f3b3c4' User entered '04 Nov 2020 05:59'	System	04 Nov 2020 11:59:29
	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(27)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(27)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 02:21:15

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(28)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	03 Nov 2020 02:03:32
User entered 'Day 28'	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(28)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T21:25:57', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '68b053fd-7eae-4362-a568-caa5ca87990e'	System	05 Nov 2020 03:26:01
User entered 'Does not interfere with activity (2)'	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(28)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-04T21:25:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '68b053fd-7eae-4362-a568-caa5ca87990e' User entered '04 Nov 2020 21:25'	System	05 Nov 2020 03:26:01
	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(28)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Nov 2020 12:00'	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(28)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Nov 2020 11:59'	System	03 Nov 2020 02:03:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(29)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	04 Nov 2020 11:59:29
User entered 'Day 29'	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(29)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-05T22:06:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ecac174a-6720-4a1f-93c7-01832b4b3b3b'	System	06 Nov 2020 04:06:32
User entered 'Does not interfere with activity (2)'	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(29)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-05T22:06:30', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ecac174a-6720-4a1f-93c7-01832b4b3b3b' User entered '05 Nov 2020 22:06'	System	06 Nov 2020 04:06:32
	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(29)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(29)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 11:59:29

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(30)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	05 Nov 2020 03:26:01
User entered 'Day 30'	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(30)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(30)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(30)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(30)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 03:26:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(31)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	06 Nov 2020 04:06:32
User entered 'Day 31'	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(31)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-07T12:00:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '175284cf-bc19-4a78-8090-8375647d6afb'	System	07 Nov 2020 18:00:48
User entered 'Does not interfere with activity (2)'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(31)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-07T12:00:45', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '175284cf-bc19-4a78-8090-8375647d6afb' User entered '07 Nov 2020 12:00'	System	07 Nov 2020 18:00:48
	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(31)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(31)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 04:06:32

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(32)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	07 Nov 2020 18:00:48
User entered 'Day 32'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(32)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-08T12:05:45', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '84c863db-4853-4e92-83c2-f3f1dbfeaad5'	System	08 Nov 2020 18:05:54
User entered 'Does not interfere with activity (2)'	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(32)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-08T12:05:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '84c863db-4853-4e92-83c2-f3f1dbfeaad5' User entered '08 Nov 2020 12:05'	System	08 Nov 2020 18:05:54
	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(32)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(32)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(33)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	07 Nov 2020 18:00:48
User entered 'Day 33'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(33)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-09T19:12:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5e40fc33-91cd-470e-8bb9-ca0e12ec2ad1'	System	10 Nov 2020 01:12:51
User entered 'Does not interfere with activity (2)'	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(33)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-09T19:12:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5e40fc33-91cd-470e-8bb9-ca0e12ec2ad1' User entered '09 Nov 2020 19:12'	System	10 Nov 2020 01:12:51
	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(33)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(33)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:00:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(34)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Nov 2020 18:05:54
User entered 'Day 34'	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(34)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-10T20:00:09', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a031f20c-17ef-4bc3-b74d-d18b52995899'	System	11 Nov 2020 02:00:17
User entered 'Does not interfere with activity (2)'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(34)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-10T20:00:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a031f20c-17ef-4bc3-b74d-d18b52995899'	System	11 Nov 2020 02:00:17
User entered '10 Nov 2020 20:00'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(34)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '10 Nov 2020 12:00'	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(34)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Nov 2020 11:59'	System	08 Nov 2020 18:05:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(35)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	10 Nov 2020 01:12:51
User entered 'Day 35'	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(35)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-11T21:13:04', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8746b7fc-54bb-41f3-9afd-4999c74d2463'	System	12 Nov 2020 03:13:09
User entered 'Does not interfere with activity (2)'	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(35)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-11T21:13:07', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8746b7fc-54bb-41f3-9afd-4999c74d2463' User entered '11 Nov 2020 21:13'	System	12 Nov 2020 03:13:09
	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(35)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(35)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 01:12:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(36)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	11 Nov 2020 02:00:17
User entered 'Day 36'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(36)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-12T20:00:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0ea12978-4136-4fc0-b917-1eef16cfcf6c'	System	13 Nov 2020 02:00:52
User entered 'Does not interfere with activity (2)'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(36)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-12T20:00:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0ea12978-4136-4fc0-b917-1eef16cfcf6c'	System	13 Nov 2020 02:00:52
User entered '12 Nov 2020 20:00'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(36)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(36)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 02:00:17

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(37)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	12 Nov 2020 03:13:09
User entered 'Day 37'	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(37)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-13T20:02:19', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ced8e592-0841-48a7-9f40-08c6fe3ea2d7'	System	14 Nov 2020 02:02:24
User entered 'Does not interfere with activity (2)'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(37)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-13T20:02:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ced8e592-0841-48a7-9f40-08c6fe3ea2d7'	System	14 Nov 2020 02:02:24
User entered '13 Nov 2020 20:02'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(37)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(37)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 03:13:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(38)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	13 Nov 2020 02:00:52
User entered 'Day 38'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(38)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-14T22:36:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f4b1de7-a0ac-4ae0-a62b-bcd95d289638'	System	15 Nov 2020 04:36:08
User entered 'Does not interfere with activity (2)'	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(38)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-14T22:36:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '6f4b1de7-a0ac-4ae0-a62b-bcd95d289638' User entered '14 Nov 2020 22:36'	System	15 Nov 2020 04:36:08
	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(38)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '14 Nov 2020 12:00'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(38)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Nov 2020 11:59'	System	13 Nov 2020 02:00:52

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(39)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	14 Nov 2020 02:02:24
User entered 'Day 39'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(39)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-15T20:00:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0a0bf08-98be-4488-a99b-8e339d64c6b7'	System	16 Nov 2020 02:00:28
User entered 'Does not interfere with activity (2)'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(39)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-15T20:00:23', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b0a0bf08-98be-4488-a99b-8e339d64c6b7'	System	16 Nov 2020 02:00:28
User entered '15 Nov 2020 20:00'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(39)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(39)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 02:02:24

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(40)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	15 Nov 2020 04:36:08
User entered 'Day 40'	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(40)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-16T20:00:56', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2089214b-8c80-4da9-8f3c-f356766aede4'	System	17 Nov 2020 02:01:05
User entered 'Does not interfere with activity (2)'	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(40)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-16T20:00:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2089214b-8c80-4da9-8f3c-f356766aede4' User entered '16 Nov 2020 20:00'	System	17 Nov 2020 02:01:05
	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(40)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(40)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 04:36:08

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(41)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	16 Nov 2020 02:00:28
User entered 'Day 41'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(41)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-17T21:31:41', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c605998b-c024-4bde-a838-0e7ec8a1fadd'	System	18 Nov 2020 03:31:48
User entered 'Does not interfere with activity (2)'	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(41)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-17T21:31:44', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c605998b-c024-4bde-a838-0e7ec8a1fadd' User entered '17 Nov 2020 21:31'	System	18 Nov 2020 03:31:48
	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(41)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(41)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 02:00:28

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(42)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	17 Nov 2020 02:01:05
User entered 'Day 42'	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(42)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-18T20:01:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '42b30488-45c8-4b68-86bd-c0936e4b25ce'	System	19 Nov 2020 02:01:51
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(42)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-18T20:01:49', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '42b30488-45c8-4b68-86bd-c0936e4b25ce' User entered '18 Nov 2020 20:01'	System	19 Nov 2020 02:01:51
	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(42)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(42)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 02:01:05

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(43)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	18 Nov 2020 03:31:48
User entered 'Day 43'	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(43)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-19T20:00:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5cfa50b6-7917-4ca8-a478-6211e208a7a2'	System	20 Nov 2020 02:00:55
User entered 'Does not interfere with activity (2)'	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(43)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-19T20:00:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5cfa50b6-7917-4ca8-a478-6211e208a7a2' User entered '19 Nov 2020 20:00'	System	20 Nov 2020 02:00:55
	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(43)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(43)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 03:31:48

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(44)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	19 Nov 2020 02:01:51
User entered 'Day 44'	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(44)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-20T20:00:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '37506698-34d1-43e6-94ff-c991e14d4962'	System	21 Nov 2020 02:00:34
User entered 'Does not interfere with activity (2)'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(44)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-20T20:00:31', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '37506698-34d1-43e6-94ff-c991e14d4962'	System	21 Nov 2020 02:00:34
User entered '20 Nov 2020 20:00'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(44)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(44)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 02:01:51

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(45)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	20 Nov 2020 02:00:55
User entered 'Day 45'	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(45)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-21T20:02:50', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ced4e5d4-03a5-4769-956d-6feb3404edd3'	System	22 Nov 2020 02:03:01
User entered 'Does not interfere with activity (2)'	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(45)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-21T20:02:57', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'ced4e5d4-03a5-4769-956d-6feb3404edd3' User entered '21 Nov 2020 20:02'	System	22 Nov 2020 02:03:01
	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(45)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(45)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 02:00:55

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(46)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	21 Nov 2020 02:00:34
User entered 'Day 46'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(46)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-22T20:00:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a4eed63-ae1d-4d9d-b624-0283d718215c'	System	23 Nov 2020 02:00:38
User entered 'Does not interfere with activity (2)'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(46)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-22T20:00:36', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'a4eed63-ae1d-4d9d-b624-0283d718215c'	System	23 Nov 2020 02:00:38
User entered '22 Nov 2020 20:00'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(46)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(46)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 02:00:34

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(47)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	22 Nov 2020 02:03:01
User entered 'Day 47'	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(47)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-23T21:39:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c234d196-16fa-4167-8021-20b11a414485'	System	24 Nov 2020 03:39:53
User entered 'Does not interfere with activity (2)'	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(47)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-23T21:39:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'c234d196-16fa-4167-8021-20b11a414485' User entered '23 Nov 2020 21:39'	System	24 Nov 2020 03:39:53
	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(47)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(47)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 02:03:01

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(48)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	23 Nov 2020 02:00:38
User entered 'Day 48'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(48)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-24T21:48:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5f1ad5e6-a0f8-4d90-84ee-b65c0cd32e0d'	System	25 Nov 2020 03:48:22
User entered 'Does not interfere with activity (2)'	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(48)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-24T21:48:17', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '5f1ad5e6-a0f8-4d90-84ee-b65c0cd32e0d' User entered '24 Nov 2020 21:48'	System	25 Nov 2020 03:48:22
	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(48)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(48)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(49)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	24 Nov 2020 03:39:53
User entered 'Day 49'	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(49)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-25T20:12:26', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd4585879-7b2f-4dc7-953d-5fe9b552d6ae'	System	26 Nov 2020 02:12:33
User entered 'Does not interfere with activity (2)'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(49)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-25T20:12:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd4585879-7b2f-4dc7-953d-5fe9b552d6ae'	System	26 Nov 2020 02:12:33
User entered '25 Nov 2020 20:12'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(49)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '25 Nov 2020 12:00'	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(49)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Nov 2020 11:59'	System	24 Nov 2020 03:39:53

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(50)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	25 Nov 2020 03:48:22
User entered 'Day 50'	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(50)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-26T21:26:14', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2a627fa1-8ca7-4b89-8fd0-9715568dc6d8'	System	27 Nov 2020 03:26:19
User entered 'Does not interfere with activity (2)'	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(50)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-26T21:26:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2a627fa1-8ca7-4b89-8fd0-9715568dc6d8' User entered '26 Nov 2020 21:26'	System	27 Nov 2020 03:26:19
	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(50)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '26 Nov 2020 12:00'	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(50)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Nov 2020 11:59'	System	25 Nov 2020 03:48:22

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(51)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	26 Nov 2020 02:12:33
User entered 'Day 51'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(51)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-28T09:35:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '984b2645-2ec7-4839-9568-ebcc0a819c63'	System	28 Nov 2020 15:35:31
User entered 'Does not interfere with activity (2)'	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(51)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-28T09:35:26', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '984b2645-2ec7-4839-9568-ebcc0a819c63' User entered '28 Nov 2020 09:35'	System	28 Nov 2020 15:35:31
	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(51)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '27 Nov 2020 12:00'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(51)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Nov 2020 11:59'	System	26 Nov 2020 02:12:33

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(52)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	27 Nov 2020 03:26:19
User entered 'Day 52'	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(52)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(52)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(52)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '28 Nov 2020 12:00'	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(52)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Nov 2020 11:59'	System	27 Nov 2020 03:26:19

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(53)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	28 Nov 2020 15:35:31
User entered 'Day 53'	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(53)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-29T12:00:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '72c145b7-8eb4-41ca-b4b2-14afccdc0221'	System	29 Nov 2020 18:00:41
User entered 'Does not interfere with activity (2)'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(53)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-29T12:00:39', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '72c145b7-8eb4-41ca-b4b2-14afccdc0221' User entered '29 Nov 2020 12:00'	System	29 Nov 2020 18:00:41
	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(53)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '29 Nov 2020 12:00'	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(53)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Nov 2020 11:59'	System	28 Nov 2020 15:35:31

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(54)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	29 Nov 2020 18:00:41
User entered 'Day 54'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(54)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-30T20:01:47', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4cb9b72b-f89e-4fa5-a5fd-9e265863a426'	System	01 Dec 2020 02:01:54
User entered 'Does not interfere with activity (2)'	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(54)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-30T20:01:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4cb9b72b-f89e-4fa5-a5fd-9e265863a426' User entered '30 Nov 2020 20:01'	System	01 Dec 2020 02:01:54
	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(54)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '30 Nov 2020 12:00'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(54)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Dec 2020 11:59'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(55)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	29 Nov 2020 18:00:41
User entered 'Day 55'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(55)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-01T20:00:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '15dc3e24-7415-43d8-8397-d0e8c6d9475f'	System	02 Dec 2020 02:00:57
User entered 'Does not interfere with activity (2)'	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(55)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-01T20:00:53', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '15dc3e24-7415-43d8-8397-d0e8c6d9475f' User entered '01 Dec 2020 20:00'	System	02 Dec 2020 02:00:57
	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(55)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '01 Dec 2020 12:00'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(55)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Dec 2020 11:59'	System	29 Nov 2020 18:00:41

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(56)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	01 Dec 2020 02:01:54
User entered 'Day 56'	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(56)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T06:28:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9b2d6377-1d95-4930-a62b-9b1e19c2b806'	System	03 Dec 2020 12:28:09
User entered 'Does not interfere with activity (2)'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(56)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T06:28:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '9b2d6377-1d95-4930-a62b-9b1e19c2b806'	System	03 Dec 2020 12:28:09
User entered '03 Dec 2020 06:28'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(56)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '02 Dec 2020 12:00'	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(56)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Dec 2020 11:59'	System	01 Dec 2020 02:01:54

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(57)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	02 Dec 2020 02:00:57
User entered 'Day 57'	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(57)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T12:00:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4228d4b3-c722-4e5a-8787-c91ebdfdb5bf'	System	03 Dec 2020 18:00:56
User entered 'Does not interfere with activity (2)'	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(57)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T12:00:53', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4228d4b3-c722-4e5a-8787-c91ebdfdb5bf' User entered '03 Dec 2020 12:00'	System	03 Dec 2020 18:00:56
	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(57)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '03 Dec 2020 12:00'	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(57)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Dec 2020 11:59'	System	02 Dec 2020 02:00:57

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(58)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	03 Dec 2020 12:28:09
User entered 'Day 58'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(58)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-04T21:20:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd78acea6-ad54-4eba-9fed-52a5ba246c52'	System	05 Dec 2020 03:20:30
User entered 'Does not interfere with activity (2)'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(58)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-04T21:20:26', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'd78acea6-ad54-4eba-9fed-52a5ba246c52'	System	05 Dec 2020 03:20:30
User entered '04 Dec 2020 21:20'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(58)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '04 Dec 2020 12:00'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(58)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Dec 2020 11:59'	System	03 Dec 2020 12:28:09

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(59)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	03 Dec 2020 18:00:56
User entered 'Day 59'	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(59)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-05T20:16:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2329ea1d-b93e-403f-ac25-576bfa9e05ea'	System	06 Dec 2020 02:16:50
User entered 'Does not interfere with activity (2)'	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(59)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-05T20:16:48', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2329ea1d-b93e-403f-ac25-576bfa9e05ea' User entered '05 Dec 2020 20:16'	System	06 Dec 2020 02:16:50
	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(59)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '05 Dec 2020 12:00'	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(59)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Dec 2020 11:59'	System	03 Dec 2020 18:00:56

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(60)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	05 Dec 2020 03:20:30
User entered 'Day 60'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(60)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-06T20:00:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'af877b93-31ce-4acb-aa8a-972bc4826c4e'	System	07 Dec 2020 02:00:38
User entered 'Does not interfere with activity (2)'	System	07 Dec 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(60)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-06T20:00:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'af877b93-31ce-4acb-aa8a-972bc4826c4e' User entered '06 Dec 2020 20:00'	System	07 Dec 2020 02:00:38
	System	07 Dec 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(60)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '06 Dec 2020 12:00'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(60)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Dec 2020 11:59'	System	05 Dec 2020 03:20:30

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(61)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	06 Dec 2020 02:16:50
User entered 'Day 61'	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(61)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-07T17:22:57', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '742f36e0-efb1-4a09-b25a-428ac17fd311'	System	07 Dec 2020 23:23:02
User entered 'Does not interfere with activity (2)'	System	07 Dec 2020 23:23:02

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(61)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-07T17:22:59', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '742f36e0-efb1-4a09-b25a-428ac17fd311' User entered '07 Dec 2020 17:22'	System	07 Dec 2020 23:23:02
	System	07 Dec 2020 23:23:02

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(61)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '07 Dec 2020 12:00'	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(61)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Dec 2020 11:59'	System	06 Dec 2020 02:16:50

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(62)

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	07 Dec 2020 02:00:38
User entered 'Day 62'	System	07 Dec 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(62)

Generated On: 11 Aug 2021 22:20:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-08T21:26:02', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b6dbc4f2-304e-4319-9b4b-d352538544c3'	System	09 Dec 2020 03:26:07
User entered 'None (1)'	System	09 Dec 2020 03:26:07

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(62)

Generated On: 11 Aug 2021 22:20:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-08T21:26:04', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'b6dbc4f2-304e-4319-9b4b-d352538544c3' User entered '08 Dec 2020 21:26'	System	09 Dec 2020 03:26:07
	System	09 Dec 2020 03:26:07

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(62)

Generated On: 11 Aug 2021 22:20:12

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '08 Dec 2020 12:00'	System	07 Dec 2020 02:00:38

US3312551

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(62)

Generated On: 11 Aug 2021 22:20:12

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
User entered '09 Dec 2020 11:59'	System	07 Dec 2020 02:00:38

US3312551

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:01:41

US3312551

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:01:41

US3312551

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:01:41

US3312551

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:01:41

US3312551

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:01:44

US3312551

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'I'	System	20 Oct 2020 13:01:44

US3312551

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:54:37

US3312551

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:54:37

US3312551

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:54:37

US3312551

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:54:37

US3312551

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:54:23

US3312551

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'I'	System	27 Oct 2020 14:54:23

US3312551

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:49:49

US3312551

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:49:49

US3312551

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:49:49

US3312551

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:49:49

US3312551

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:49:54

US3312551

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'I'	System	04 Nov 2020 14:49:54

US3312551

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:34

US3312551

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:34

US3312551

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:34

US3312551

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'VISIT3'	System	06 Nov 2020 16:05:34

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '10:36'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered '05 Nov 2020 10:36'	System	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '68'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'bpm'	System	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '14'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'breaths/min'	System	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '128'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'mmHg'	System	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '77'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'mmHg'	System	06 Nov 2020 16:05:57

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43

US3312551

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43

US3312551

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:06:02

US3312551

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:06:02

US3312551

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:06:17

US3312551

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:06:17

US3312551

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered '11:17'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:06:17

US3312551

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered '05 Nov 2020 11:17'	System	06 Nov 2020 16:06:17

US3312551

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:06:38

US3312551

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'I'	System	06 Nov 2020 16:06:38

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 64'	System	08 Sep 2020 21:24:35

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-08T12:05:54', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '427d31df-8d23-4c45-b817-aea899fc93e4'	System	08 Nov 2020 18:06:05
User entered 'No (N)'	System	08 Nov 2020 18:06:05

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-08T12:05:57', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '427d31df-8d23-4c45-b817-aea899fc93e4'	System	08 Nov 2020 18:06:05
User entered 'No (N)'	System	08 Nov 2020 18:06:05

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-08T12:06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '427d31df-8d23-4c45-b817-aea899fc93e4' User entered '08 Nov 2020 12:06:00'	System	08 Nov 2020 18:06:05
	System	08 Nov 2020 18:06:05

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 21:24:35

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered 'Day 71'	System	08 Sep 2020 21:24:35

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-15T06:30:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '836b431e-484c-47cd-8d25-541714ffd95d' User entered 'No (N)'	System	15 Nov 2020 12:30:34
	System	15 Nov 2020 12:30:34

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-15T06:30:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '836b431e-484c-47cd-8d25-541714ffd95d'	System	15 Nov 2020 12:30:34
User entered 'No (N)'	System	15 Nov 2020 12:30:34

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-15T06:30:32', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '836b431e-484c-47cd-8d25-541714ffd95d' User entered '15 Nov 2020 06:30:32'	System	15 Nov 2020 12:30:34
	System	15 Nov 2020 12:30:34

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 21:24:35

US3312551

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:07:41
Data entry locked.	System	08 Sep 2020 21:24:35
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 21:24:35

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-20T20:00:36', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '65c3c03b-cb36-4b81-a23c-a965fb04abba' User entered 'No (N)'	System	21 Nov 2020 02:00:45
	System	21 Nov 2020 02:00:45

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-20T20:00:40', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '65c3c03b-cb36-4b81-a23c-a965fb04abba' User entered 'No (N)'	System	21 Nov 2020 02:00:45
	System	21 Nov 2020 02:00:45

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-20T20:00:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '65c3c03b-cb36-4b81-a23c-a965fb04abba' User entered '20 Nov 2020 20:00:43'	System	21 Nov 2020 02:00:45
	System	21 Nov 2020 02:00:45

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-26T21:26:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '38a1c8e4-4b73-4997-8eac-89cb7e9df560'	System	27 Nov 2020 03:26:31
User entered 'No (N)'	System	27 Nov 2020 03:26:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-26T21:26:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '38a1c8e4-4b73-4997-8eac-89cb7e9df560'	System	27 Nov 2020 03:26:31
User entered 'No (N)'	System	27 Nov 2020 03:26:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-11-26T21:26:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '38a1c8e4-4b73-4997-8eac-89cb7e9df560'	System	27 Nov 2020 03:26:31
User entered '26 Nov 2020 21:26:28'	System	27 Nov 2020 03:26:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T06:28:14', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3da73a45-4057-499a-94a7-e29a45cbc6fc' User entered 'No (N)'	System	03 Dec 2020 12:28:28
	System	03 Dec 2020 12:28:28

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T06:28:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3da73a45-4057-499a-94a7-e29a45cbc6fc' User entered 'No (N)'	System	03 Dec 2020 12:28:28
	System	03 Dec 2020 12:28:28

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-03T06:28:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3da73a45-4057-499a-94a7-e29a45cbc6fc' User entered '03 Dec 2020 06:28:25'	System	03 Dec 2020 12:28:28
	System	03 Dec 2020 12:28:28

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-10T16:50:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f2197537-610d-4d0b-9116-feb81c398927'	System	10 Dec 2020 22:50:31
User entered 'Yes (Y)'	System	10 Dec 2020 22:50:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-10T16:50:12', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f2197537-610d-4d0b-9116-feb81c398927'	System	10 Dec 2020 22:50:31
User entered 'No (N)'	System	10 Dec 2020 22:50:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-10T16:50:16', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f2197537-610d-4d0b-9116-feb81c398927'	System	10 Dec 2020 22:50:31
User entered 'No (N)'	System	10 Dec 2020 22:50:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-10T16:50:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f2197537-610d-4d0b-9116-feb81c398927'	System	10 Dec 2020 22:50:31
User entered 'No (N)'	System	10 Dec 2020 22:50:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-10T16:50:24', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'f2197537-610d-4d0b-9116-feb81c398927' User entered '10 Dec 2020 16:50:24'	System	10 Dec 2020 22:50:31
	System	10 Dec 2020 22:50:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-17T18:40:51', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3691303f-33ed-4dc3-bb80-fb9d3d725416' User entered 'No (N)'	System	18 Dec 2020 00:41:16
	System	18 Dec 2020 00:41:16

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-17T18:40:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3691303f-33ed-4dc3-bb80-fb9d3d725416' User entered 'Yes (Y)'	System	18 Dec 2020 00:41:16
	System	18 Dec 2020 00:41:16

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-17T18:41:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3691303f-33ed-4dc3-bb80-fb9d3d725416'	System	18 Dec 2020 00:41:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 00:41:16

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-17T18:41:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3691303f-33ed-4dc3-bb80-fb9d3d725416' User entered '17 Dec 2020 18:41:06'	System	18 Dec 2020 00:41:16
	System	18 Dec 2020 00:41:16

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-27T17:59:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '40bcd648-b65a-4622-9bdf-a3d3e7762bfc' User entered 'No (N)'	System	27 Dec 2020 23:59:37
	System	27 Dec 2020 23:59:37

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-27T17:59:31', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '40bcd648-b65a-4622-9bdf-a3d3e7762bfc' User entered 'No (N)'	System	27 Dec 2020 23:59:37
	System	27 Dec 2020 23:59:37

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-27T17:59:34', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '40bcd648-b65a-4622-9bdf-a3d3e7762bfc' User entered '27 Dec 2020 17:59:34'	System	27 Dec 2020 23:59:37
	System	27 Dec 2020 23:59:37

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-31T06:22:05', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '7c968a9a-94cf-43b7-8c22-d5a1512bf4d8'	System	31 Dec 2020 12:22:13
User entered 'No (N)'	System	31 Dec 2020 12:22:13

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-31T06:22:07', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '7c968a9a-94cf-43b7-8c22-d5a1512bf4d8'	System	31 Dec 2020 12:22:13
User entered 'No (N)'	System	31 Dec 2020 12:22:13

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2020-12-31T06:22:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '7c968a9a-94cf-43b7-8c22-d5a1512bf4d8' User entered '31 Dec 2020 06:22:10'	System	31 Dec 2020 12:22:13
	System	31 Dec 2020 12:22:13

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-10T17:59:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4d08a839-0a3a-451e-a464-934f80409dac' User entered 'No (N)'	System	10 Jan 2021 23:59:22
	System	10 Jan 2021 23:59:22

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-10T17:59:15', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4d08a839-0a3a-451e-a464-934f80409dac' User entered 'No (N)'	System	10 Jan 2021 23:59:22
	System	10 Jan 2021 23:59:22

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-10T17:59:18', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4d08a839-0a3a-451e-a464-934f80409dac' User entered '10 Jan 2021 17:59:18'	System	10 Jan 2021 23:59:22
	System	10 Jan 2021 23:59:22

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-14T06:46:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dacadb1e-a2a5-4b69-94c0-1e245c19ee41'	System	14 Jan 2021 12:46:41
User entered 'No (N)'	System	14 Jan 2021 12:46:41

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-14T06:46:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dacadb1e-a2a5-4b69-94c0-1e245c19ee41'	System	14 Jan 2021 12:46:41
User entered 'No (N)'	System	14 Jan 2021 12:46:41

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-14T06:46:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'dacadb1e-a2a5-4b69-94c0-1e245c19ee41' User entered '14 Jan 2021 06:46:35'	System	14 Jan 2021 12:46:41
	System	14 Jan 2021 12:46:41

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-23T12:00:30', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2d4045fa-efbd-49d6-961b-19ddb8832885'	System	23 Jan 2021 18:00:54
User entered 'No (N)'	System	23 Jan 2021 18:00:54

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-23T12:00:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2d4045fa-efbd-49d6-961b-19ddb8832885'	System	23 Jan 2021 18:00:54
User entered 'No (N)'	System	23 Jan 2021 18:00:54

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-23T12:00:35', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2d4045fa-efbd-49d6-961b-19ddb8832885' User entered '23 Jan 2021 12:00:35'	System	23 Jan 2021 18:00:54
	System	23 Jan 2021 18:00:54

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-29T19:55:37', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2101bf9d-e569-451a-ae8e-d16a38237e03'	System	30 Jan 2021 01:56:17
User entered 'No (N)'	System	30 Jan 2021 01:56:17

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-29T19:56:03', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2101bf9d-e569-451a-ae8e-d16a38237e03'	System	30 Jan 2021 01:56:17
User entered 'No (N)'	System	30 Jan 2021 01:56:17

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-01-29T19:56:06', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2101bf9d-e569-451a-ae8e-d16a38237e03' User entered '29 Jan 2021 19:56:06'	System	30 Jan 2021 01:56:17

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-07T18:11:22', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '76432019-07fe-4b91-9717-6d0d2be6847d' User entered 'No (N)'	System	08 Feb 2021 00:11:38
	System	08 Feb 2021 00:11:38

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-07T18:11:25', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '76432019-07fe-4b91-9717-6d0d2be6847d'	System	08 Feb 2021 00:11:38
User entered 'No (N)'	System	08 Feb 2021 00:11:38

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-07T18:11:28', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '76432019-07fe-4b91-9717-6d0d2be6847d' User entered '07 Feb 2021 18:11:28'	System	08 Feb 2021 00:11:38
	System	08 Feb 2021 00:11:38

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-12T15:37:29', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '19d9cbb5-be80-4ca5-9536-1575ef46779b' User entered 'No (N)'	System	12 Feb 2021 21:37:37
	System	12 Feb 2021 21:37:37

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-12T15:37:27', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '19d9cbb5-be80-4ca5-9536-1575ef46779b' User entered 'No (N)'	System	12 Feb 2021 21:37:37
	System	12 Feb 2021 21:37:37

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-12T15:37:33', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '19d9cbb5-be80-4ca5-9536-1575ef46779b' User entered '12 Feb 2021 15:37:33'	System	12 Feb 2021 21:37:37
	System	12 Feb 2021 21:37:37

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-18T21:21:21', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8c5bd5a2-5999-43fe-9f11-9b16ed9c88de' User entered 'Yes (Y)'	System	19 Feb 2021 03:22:27
	System	19 Feb 2021 03:22:27

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-18T21:21:43', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8c5bd5a2-5999-43fe-9f11-9b16ed9c88de' User entered 'No (N)'	System	19 Feb 2021 03:22:27
	System	19 Feb 2021 03:22:27

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-18T21:21:46', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8c5bd5a2-5999-43fe-9f11-9b16ed9c88de' User entered 'No (N)'	System	19 Feb 2021 03:22:27
	System	19 Feb 2021 03:22:27

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-18T21:21:58', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8c5bd5a2-5999-43fe-9f11-9b16ed9c88de' User entered 'Yes (Y)'	System	19 Feb 2021 03:22:27
	System	19 Feb 2021 03:22:27

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-18T21:22:10', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8c5bd5a2-5999-43fe-9f11-9b16ed9c88de'	System	19 Feb 2021 03:22:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Feb 2021 03:22:27

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-18T21:22:13', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '8c5bd5a2-5999-43fe-9f11-9b16ed9c88de' User entered '18 Feb 2021 21:22:13'	System	19 Feb 2021 03:22:27
	System	19 Feb 2021 03:22:27

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-28T18:49:59-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '33f7cf5d-b4e5-4132-a368-60d0a2237649'	System	01 Mar 2021 00:50:11
User entered 'No (N)'	System	01 Mar 2021 00:50:11

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-28T18:50:01-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '33f7cf5d-b4e5-4132-a368-60d0a2237649'	System	01 Mar 2021 00:50:11
User entered 'No (N)'	System	01 Mar 2021 00:50:11

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-28T18:50:04-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '33f7cf5d-b4e5-4132-a368-60d0a2237649' User entered '28 Feb 2021 18:50:04'	System	01 Mar 2021 00:50:11
	System	01 Mar 2021 00:50:11

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-11T06:20:32-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4c67e383-1472-4279-b4e9-a7ff35ffa723'	System	11 Mar 2021 12:20:40
User entered 'No (N)'	System	11 Mar 2021 12:20:40

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-11T06:20:34-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4c67e383-1472-4279-b4e9-a7ff35ffa723'	System	11 Mar 2021 12:20:40
User entered 'No (N)'	System	11 Mar 2021 12:20:40

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-11T06:20:36-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '4c67e383-1472-4279-b4e9-a7ff35ffa723'	System	11 Mar 2021 12:20:40
User entered '11 Mar 2021 06:20:36'	System	11 Mar 2021 12:20:40

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-20T12:00:12-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '14a47b1e-11d2-4b15-9b4d-17543d8cb972'	System	20 Mar 2021 17:00:20
User entered 'No (N)'	System	20 Mar 2021 17:00:20

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-20T12:00:14-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '14a47b1e-11d2-4b15-9b4d-17543d8cb972'	System	20 Mar 2021 17:00:20
User entered 'No (N)'	System	20 Mar 2021 17:00:20

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-20T12:00:16-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '14a47b1e-11d2-4b15-9b4d-17543d8cb972'	System	20 Mar 2021 17:00:20
User entered '20 Mar 2021 12:00:16'	System	20 Mar 2021 17:00:20

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-25T07:35:19-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1560b478-7740-427c-970e-d099eb87a0b8'	System	25 Mar 2021 12:35:31
User entered 'No (N)'	System	25 Mar 2021 12:35:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-25T07:35:21-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1560b478-7740-427c-970e-d099eb87a0b8'	System	25 Mar 2021 12:35:31
User entered 'No (N)'	System	25 Mar 2021 12:35:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-03-25T07:35:24-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '1560b478-7740-427c-970e-d099eb87a0b8' User entered '25 Mar 2021 07:35:24'	System	25 Mar 2021 12:35:31
	System	25 Mar 2021 12:35:31

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-03T12:00:57-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3e17aa7b-b204-4d9c-b0c2-344550afdafc' User entered 'No (N)'	System	03 Apr 2021 17:01:46

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-03T12:00:59-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3e17aa7b-b204-4d9c-b0c2-344550afdafc'	System	03 Apr 2021 17:01:46
User entered 'No (N)'	System	03 Apr 2021 17:01:46

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-03T12:01:02-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '3e17aa7b-b204-4d9c-b0c2-344550afdafa'	System	03 Apr 2021 17:01:46
User entered '03 Apr 2021 12:01:02'	System	03 Apr 2021 17:01:46

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-09T20:03:23-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e006db33-f727-4961-a1c4-ab4cb62ea327'	System	10 Apr 2021 01:10:08
User entered 'No (N)'	System	10 Apr 2021 01:10:08

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-09T20:04:18-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e006db33-f727-4961-a1c4-ab4cb62ea327'	System	10 Apr 2021 01:10:08
User entered 'No (N)'	System	10 Apr 2021 01:10:08

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-09T20:04:20-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: 'e006db33-f727-4961-a1c4-ab4cb62ea327'	System	10 Apr 2021 01:10:08
User entered '09 Apr 2021 20:04:20'	System	10 Apr 2021 01:10:08

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-15T06:20:26-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '74bad627-dabd-4357-90bc-0015dc492b4a'	System	15 Apr 2021 11:20:34
User entered 'No (N)'	System	15 Apr 2021 11:20:34

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-15T06:20:28-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '74bad627-dabd-4357-90bc-0015dc492b4a'	System	15 Apr 2021 11:20:34
User entered 'No (N)'	System	15 Apr 2021 11:20:34

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-15T06:20:30-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '74bad627-dabd-4357-90bc-0015dc492b4a'	System	15 Apr 2021 11:20:34
User entered '15 Apr 2021 06:20:30'	System	15 Apr 2021 11:20:34

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-22T14:57:43-07:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2a9acbc8-4663-4755-af54-43a55676fee3'	System	22 Apr 2021 21:57:50
User entered 'No (N)'	System	22 Apr 2021 21:57:50

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-22T14:57:45-07:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2a9acbc8-4663-4755-af54-43a55676fee3'	System	22 Apr 2021 21:57:50
User entered 'No (N)'	System	22 Apr 2021 21:57:50

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-22T14:57:47-07:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '2a9acbc8-4663-4755-af54-43a55676fee3'	System	22 Apr 2021 21:57:50
User entered '22 Apr 2021 14:57:47'	System	22 Apr 2021 21:57:50

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-29T15:13:01-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '04faacff-e9e7-424b-9993-b2259070a0cb'	System	29 Apr 2021 20:13:24
User entered 'No (N)'	System	29 Apr 2021 20:13:24

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-29T15:13:03-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '04faacff-e9e7-424b-9993-b2259070a0cb'	System	29 Apr 2021 20:13:24
User entered 'No (N)'	System	29 Apr 2021 20:13:24

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-04-29T15:13:19-05:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '04faacff-e9e7-424b-9993-b2259070a0cb' User entered '29 Apr 2021 15:13:19'	System	29 Apr 2021 20:13:24
	System	29 Apr 2021 20:13:24

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:22:19

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:22:19

US3312551

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:20:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:22:19
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:22:19

US3312551

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:20:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-28T18:50:12-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0cae6953-bd6a-4677-af3e-50e275b787fa'	System	01 Mar 2021 00:50:19
User entered 'No (N)'	System	01 Mar 2021 00:50:19

US3312551

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:20:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1A1937-2847-4F4D-BEBD-CE3B0E96B8D3)', Time: '2021-02-28T18:50:14-06:00', User OID: 'PatientReportedOutcome (US3312551)', ODM File OID: '0cae6953-bd6a-4677-af3e-50e275b787fa'	System	01 Mar 2021 00:50:19
User entered '28 Feb 2021 18:50:14'	System	01 Mar 2021 00:50:19

US3312551

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:17:01

US3312551

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:37:43
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Attempts were made to subject on 12/03/20, and 12/04/2020. Contact made on 12/07/2020' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 15:18:43
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Dec 2020 15:17:01
User entered '07 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:17:01

US3312551

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:17:01

US3312551

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:17:01

US3312551

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:18:54

US3312551

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:43
User entered 'I'	System	15 Dec 2020 15:18:54

US3312551

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:46:52

US3312551

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:46:52

US3312551

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:46:52

US3312551

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:46:52

US3312551

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:46:56

US3312551

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User entered 'I'	System	20 Jan 2021 17:46:56

US3312551

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4)	08 Feb 2021 20:12:43
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered '02 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 20:12:43

US3312551

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	08 Feb 2021 20:12:43

US3312551

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4)	08 Feb 2021 20:12:43
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 20:12:46

US3312551

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User entered 'I'	System	08 Feb 2021 20:12:46

US3312551

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:51:15

US3312551

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:51:15

US3312551

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:51:15

US3312551

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:20:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:51:15

US3312551

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:51:18

US3312551

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:30:28
User entered 'I'	System	05 Mar 2021 16:51:18

US3312551

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:01

US3312551

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:01

US3312551

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[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 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:01

US3312551

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered 'VISIT4'	System	26 Mar 2021 13:02:01

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'No (N)'	(b) (4)	29 Mar 2021 20:59:45
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered empty.	System	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4)	29 Mar 2021 20:59:45
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4)	29 Mar 2021 20:59:45
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4)	29 Mar 2021 20:59:45
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered empty.	System	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered empty.	System	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4)	29 Mar 2021 20:59:45
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered empty.	System	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered empty.	System	29 Mar 2021 20:59:45

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52

US3312551

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:20:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52

US3312551

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:38

US3312551

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:20:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:38

US3312551

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:58

US3312551

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:58

US3312551

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered '10:59'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:02:58

US3312551

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered '25 Mar 2021 10:59'	System	26 Mar 2021 13:02:58

US3312551

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:01:36

US3312551

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:20:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:52
User entered 'I'	System	26 Mar 2021 13:01:36

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:04:01

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:04:01

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:04:01

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:20:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User entered 'UNBLND_DECIDE'	System	26 Mar 2021 13:04:01

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Amendment 5 (Amendment 5)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:14:58
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Subject was unblinded via telephone under Amendment 5. Prior to decision visit/ signing of new informed consent.' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 13:08:44
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	26 Mar 2021 13:06:45
User entered '28 Dec 2020'	(b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:06:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User entered empty.	System	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:20:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User entered empty.	System	26 Mar 2021 13:06:45

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Mar 2021 20:59:05

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '25 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Mar 2021 20:59:05

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '10:59'	(b) (4)	29 Mar 2021 20:59:05
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:20:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User entered '25 Mar 2021 10:59'	System	29 Mar 2021 20:59:05

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:20:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Mar 2021 20:59:16

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:20:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '25 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Mar 2021 20:59:16

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:20:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '10:58' reason for change: Data Entry Error	(b) (4)	29 Mar 2021 20:59:21
User entered '10:59'	Karol Moore (b) (4)	29 Mar 2021 20:59:16
	(b) (4)	

US3312551

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:20:12

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:16:09
User entered '25 Mar 2021 10:58'	System	29 Mar 2021 20:59:21
User entered '25 Mar 2021 10:59'	System	29 Mar 2021 20:59:16

US3312551

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:20:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:23:41
User closed query 'Per DM CLR: Medical Attention was checked for DAY 43 on Diary Dose 2. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 04:07:24
Query 'Per DM CLR: Medical Attention was checked for DAY 43 on Diary Dose 2. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' answered with 'SEE AE #2' (Site from DM).	Karol Moore (b) (4) (b) (4)	20 Apr 2021 16:36:55

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:20:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Medical Attention was checked for DAY 43 on Diary Dose 2. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 00:30:29
	Carlos Fierro (b) (4)	08 Apr 2021 15:19:15
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 3 - 10OCT2020; end date: Day 61 - 07DEC2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:46:26
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 166 (18FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:46:22

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:20:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Safety Follow Up Diary Day 166 (18FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'YES MAAE SHOULD BE RECORDED. SUBJECT REPORTS SEEING PROVIDER RELATED TO POSITIVE PREGNANCY TEST' (Site from DM).	Monica Atwood (b) (4)	07 Apr 2021 19:33:22
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 3 - 10OCT2020; end date: Day 61 - 07DEC2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'PLEASE SEE AE #2 IPSILATERAL UNDERARM SWELLING ' (Site from DM).	Monica Atwood (b) (4)	07 Apr 2021 19:29:44
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 166 (18FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 06:33:10
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 3 - 10OCT2020; end date: Day 61 - 07DEC2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 01:20:01

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:20:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
Query 'Per DM CLR-RQ: Response noted. Please review confirmed Lymphadenopathy and provide specific anatomical location and laterality in reference to injection site. [eg, Injection site Lymphadenopathy, Left Axillary-contralateral (opposite injection site) Lymphadenopathy]. Update accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:03:35
User opened query 'Per DM CLR-RQ: Response noted. Please review confirmed Lymphadenopathy and provide specific anatomical location and laterality in reference to injection site. [eg, Injection site Lymphadenopathy, Left Axillary-contralateral (opposite injection site) Lymphadenopathy]. Update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:03:28
User closed query 'Per DM CLR - RQ: Site's response noted. However, it was not confirmed if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL). Otherwise, confirm that this is not Lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:03:46
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:43:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:43:49
Query 'Per DM CLR - RQ: Site's response noted. However, it was not confirmed if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL). Otherwise, confirm that this is not Lymphadenopathy.' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	17 Nov 2020 17:09:26
Data point term sent to Coder	System	17 Nov 2020 17:09:17
Coding entries removed.	Monica Atwood (b) (4) (b) (4)	17 Nov 2020 17:09:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'IPSilateral Underarm Gland Tenderness (Lymphadenopathy)' reason for change: Data Entry Error	Monica Atwood (b) (4)	17 Nov 2020 17:09:15
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary adenopathy - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 22:38:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 22:38:35
User opened query 'Per DM CLR - RQ: Site's response noted. However, it was not confirmed if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL). Otherwise, confirm that this is not Lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:44:55
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:50:06
Data point term sent to Coder	System	06 Nov 2020 16:10:54
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' answered with 'UPDATED ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:10:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 16:10:45
User entered 'IPSI LATERAL UNDERARM GLAND TENDERNESS' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 16:10:45
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 00:04:29
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Axillary pain, LLT: Axillary pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:12:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:12:39
Data point term sent to Coder	System	29 Sep 2020 20:11:16
User entered 'ipsilateral underarm tenderness'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. Please seek guidance from your local CRA in answering this query. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:46:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
Query 'Per DM CLR - RQ: Site's response noted. However, note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. Please seek guidance from your local CRA in answering this query. ' answered with 'UPDATED' (Site from DM).	(b) (4) Monica Atwood (b) (4)	07 Apr 2021 19:23:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 19:23:10
User opened query 'Per DM CLR - RQ: Site's response noted. However, note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. Please seek guidance from your local CRA in answering this query. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:09:01
User closed query 'Per DM CLR: RQ: Response noted, however, verbally reported solicited adverse reactions are considered unsolicited adverse event. Review and update response as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:11:40
Query 'Per DM CLR: RQ: Response noted, however, verbally reported solicited adverse reactions are considered unsolicited adverse event. Review and update response as appropriate.' answered with 'CORRECT AS ENTERED. AE IS AN SAR THAT WAS VERBALY REPORTED.' (Site from DM).	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 20:42:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: RQ: Response noted, however, verbally reported solicited adverse reactions are considered unsolicited adverse event. Review and update response as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:58:08
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:03:58
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' answered with 'CORRECT AS ENTERED. AE IS A SAR THAT WAS VERBALLY REPORTED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	17 Nov 2020 17:14:13
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:45:03
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '14 Sep 2020'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 20:10:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '15 Sep 2020'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 20:10:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'Related (RELATED)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'None (NONE)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'I'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	29 Sep 2020 20:10:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Sep 2020 20:10:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:20:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Sep 2020 20:10:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:25:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:25:01
User closed query 'Per DM CLR-RQ: Update noted. Review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY together with specified laterality (eg, Injection site Lymphadenopathy, etc.).' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 02:43:44
Query 'Per DM CLR-RQ: Update noted. Review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY together with specified laterality (eg, Injection site Lymphadenopathy, etc.).' answered with 'CONFIRMED CORRECT AS ENTERED. DOES NOT REFER TO LYMPHADENOPATHY.' (Site from DM).	Karol Moore (b) (4)	24 Nov 2020 22:07:27
User opened query 'Per DM CLR-RQ: Update noted. Review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY together with specified laterality (eg, Injection site Lymphadenopathy, etc.).' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:58:05
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenitis, LLT: Axillary adenitis - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 22:55:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 22:55:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:50:17
Data point term sent to Coder	System	06 Nov 2020 16:11:57
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' answered with 'UPDATED ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:11:27
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 16:11:20
User entered 'IPILATERAL UNDERARM GLAND SWELLING' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 16:11:20
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 00:04:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Swelling, LLT: Local swelling - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:00:43
Data point term sent to Coder	System	27 Oct 2020 14:59:33
User entered 'IPSILATERAL UNDERARM SWELLING'	(b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 14:55:25
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:55:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 14:59:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 14:59:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:59:34
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 14:59:23
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User entered empty.	System	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Dec 2020 20:25:36
User entered 'Yes (Y)'	Kelly Moen (b) (4)	27 Oct 2020 14:59:23
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	18 Dec 2020 20:25:36
User entered empty.	Kelly Moen (b) (4)	27 Oct 2020 14:59:23
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User entered empty.	System	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
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)	29 Dec 2020 17:16:23
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. Thanks.' (Site from DM).	Heather Barker (b) (4)	28 Dec 2020 18:25:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 18:25:43
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 09:13:08
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Kelly Moen (b) (4)	18 Dec 2020 20:25:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[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 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:59:23

US3312551

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User entered '0'	System	27 Oct 2020 14:59:23

US3312551

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15
User entered '0'	System	27 Oct 2020 14:59:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:20:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:11:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:20:12

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:38:24
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:15
User closed query ' Per DM CLR: Per Diary Dose 2 Day 1 (at home), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query ' Per DM CLR: Per Diary Dose 2 Day 1 (at home), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'CONFIRMED NO CON MED TAKEN' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:46:56
	Monica Atwood (b) (4) (b) (4)	07 Apr 2021 19:16:46
User opened query ' Per DM CLR: Per Diary Dose 2 Day 1 (at home), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 19:15:20
	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:08:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 00:28:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 00:28:38
Data point term sent to Coder	System	29 Sep 2020 20:10:15
User entered 'ibuprofen'	Karol Moore (b) (4)	29 Sep 2020 20:09:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4)	29 Sep 2020 20:09:28
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'dysmennorhea'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:09:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '600'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:09:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:09:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4)	29 Sep 2020 20:09:28
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'as needed (PRN)'	(b) (4)	29 Sep 2020 20:09:28
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4)	29 Sep 2020 20:09:28
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'un UNK 2006'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:52:09
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'UN Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:52:09
User entered empty.	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4)	29 Sep 2020 20:09:28
	Karol Moore (b) (4)	
	(b) (4)	

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User entered empty.	System	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User entered empty.	System	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:38:22
User entered empty.	System	29 Sep 2020 20:09:28

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 00:51:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 00:51:49
Data point term sent to Coder	System	22 Dec 2020 20:49:28
Coding entries removed.	Monica Atwood (b) (4)	22 Dec 2020 20:48:50
User entered 'NUVA RING (ETHINYL ESTRADIOL/ ETONOGESTREL)' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 20:48:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 22:50:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 22:50:26
Data point term sent to Coder	System	15 Dec 2020 15:29:37
Coding entries removed.	(b) (4), (b) (6)	15 Dec 2020 15:28:40
User entered 'NUVA RING (Etonogestrel 120mcg/day, ethinyl estradiol 15mcg/day)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 15:28:40

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 02:02:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 02:02:45
Data point term sent to Coder	System	29 Sep 2020 20:10:15
User entered 'nuva ring'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User closed query 'Per CDM: Previous response is "updated", however the "Dose per Administration" and "Dose unit" fields were not updated. Please review and update fields or comment accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:57:39
Query 'Per CDM: Previous response is "updated", however the "Dose per Administration" and "Dose unit" fields were not updated. Please review and update fields or comment accordingly. ' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 20:49:02
User opened query 'Per CDM: Previous response is "updated", however the "Dose per Administration" and "Dose unit" fields were not updated. Please review and update fields or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:13:10
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of ring. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:13:10
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of ring. Please verify the dose and unit, and update as appropriate. ' answered with 'Updated ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:29:56
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of ring. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:45:35
User entered 'pregnancy prophylaxis'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '0.015/0.12' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 20:48:50
User entered '1'	Monica Atwood (b) (4)	29 Sep 2020 20:10:14
	(b) (4)	

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 20:48:50
User entered 'Other (OTHER)'	Monica Atwood (b) (4)	29 Sep 2020 20:10:14
	(b) (4)	

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty; reason for change Data Entry Error	(b) (4)	22 Dec 2020 20:48:50
User entered 'ring'	Monica Atwood (b) (4)	29 Sep 2020 20:10:14
	(b) (4)	

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'every month (QM)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'intravaginal'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'un May 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:52:37
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '02 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:52:37
User entered empty.	Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User entered '1'	System	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User entered '1'	System	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:56
User entered '802 (802)'	System	29 Sep 2020 20:10:14

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 13:06:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 13:06:37
Data point term sent to Coder	System	20 Oct 2020 13:05:31
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'FEVER'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '500'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:55:39
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' answered with 'CORRECT AS ENTERED. NOT AN AE. SUBJECT NOTED TAKEN MEDICATION IN DIARY DOSE.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:36:53

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:55:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User entered empty.	System	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User entered empty.	System	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:59
User entered empty.	System	20 Oct 2020 13:05:03

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
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)	06 Nov 2020 16:10:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:10:41
Data point term sent to Coder	System	06 Nov 2020 16:08:52
User entered 'SEASONAL INFLUENZA VACCINE'	(b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'SEASONAL INFLUENZA PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'INJECTION'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User entered empty.	System	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User entered empty.	System	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:23:02
User entered empty.	System	06 Nov 2020 16:08:12

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:49:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:49:06
	(b) (4)	
Data point term sent to Coder	System	20 Jan 2021 17:48:37
User entered 'zoloft'	(b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '50'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:20:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:48:24

US3312551

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:20:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:17:19
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	08 Feb 2021 20:12:29
	(b) (4)	