

US3032108 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:53:18

All time stamps listed in this document are displayed in GMT

US3032108

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

[Participant ID](#)

US3032108

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

US3032108

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
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) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Date of Informed Consent (<i>dd MMM yyyy</i>)	05 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Oct 2020 19:30:34

Generated On: 09 Jun 2021 14:53:18

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Oct 2020 19:30:34

Generated On: 09 Jun 2021 14:53:18

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Oct 2020 19:30:34

Generated On: 09 Jun 2021 14:53:18

Condition	CHRONIC HEADACHE
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 01 Oct 2020 21:50:02

Generated On: 09 Jun 2021 14:53:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	18:07 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 18:07
Height (<i>xxx.x</i>)	157.4 cm
Weight (<i>xxx.x</i>)	48.5 kg
BMI (<i>xxx.x</i>)	19.57638 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input 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) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 16:55:45

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Date of assessment (*dd MMM yyyy*) 5 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 28 Oct 2020 15:24:23

Generated On: 09 Jun 2021 14:53:18

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	5 AUG 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) 28 Sep 2020 16:55:45

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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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 16:55:45

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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	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101356

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Oct 2020 21:50:02

Generated On: 09 Jun 2021 14:53:18

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) 01 Oct 2020 21:50:02

Generated On: 09 Jun 2021 14:53:18

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)	5 AUG 2020
Time of assessment (00:00-23:59)	18:07 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 18:07
Temperature (xxx.x)	36.8 C
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)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Oct 2020 21:50:02

Generated On: 09 Jun 2021 14:53:18

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)	5 AUG 2020
Time of assessment (00:00-23:59)	19:45 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 19:45
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	77 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 28 Oct 2020 15:24:23

Generated On: 09 Jun 2021 14:53:18

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) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

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) 05 AUG 2020

What was the treatment time? (00:00-23:59) 19:12 (24 HR)

Treatment Date and Time (derived) 05 AUG 2020 19:12

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) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 AUG 2020

Collection time (00:00-23:59)

18:32 (24 HR)

Collection date and time (derived)

5 AUG 2020 18:32

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:21	5 AUG 2020 18:21
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

98.4 °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

05 AUG 2020 19:45

PC Open Date & Time

05 AUG 2020 19:32

PC Close Date & Time

05 AUG 2020 22:02

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °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	06 AUG 2020 04:22
PC Open Date & Time	05 AUG 2020 22:57
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

06 AUG 2020 12:06

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 15:57

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 00:32

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 20:55

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

97.7 °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

10 AUG 2020 12:32

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

98.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 AUG 2020 12:21

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:02

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 19:45

PC Open Date & Time

05 AUG 2020 19:32

PC Close Date & Time

05 AUG 2020 22:02

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

06 AUG 2020 04:22

PC Open Date & Time

05 AUG 2020 22:57

PC Close Date & Time

06 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

06 AUG 2020 12:06

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

07 AUG 2020 15:57

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

09 AUG 2020 00:32

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

09 AUG 2020 20:55

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

10 AUG 2020 12:32

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

11 AUG 2020 12:21

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 19:46
PC Open Date & Time	05 AUG 2020 19:32
PC Close Date & Time	05 AUG 2020 22:02

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 04:22
PC Open Date & Time	05 AUG 2020 22:57
PC Close Date & Time	06 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

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 ☒

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 12:07
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 15:57
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

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 ☒

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 00:33
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:56
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 12:33
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

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 ☒

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 12 AUG 2020 12:02

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 13 AUG 2020 12:17

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 14 AUG 2020 13:36

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 15 AUG 2020 18:04

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 16 AUG 2020 16:08

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

17 AUG 2020 13:39

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp

18 AUG 2020 23:43

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☒

PC Time Stamp

19 AUG 2020 16:28

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 AUG 2020 12:02

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 9

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 AUG 2020 12:18

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 12 AUG 2020 12:02

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	13 AUG 2020 12:18
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PC Open Date & Time	13 AUG 2020 12:00
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PC Close Date & Time	14 AUG 2020 11:59
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US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 14 AUG 2020 13:36

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 12 AUG 2020 12:02

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

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	12 AUG 2020 12:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

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	13 AUG 2020 12:18
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

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	14 AUG 2020 13:36
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:53:18

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	16 AUG 2020 16:08
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

17 AUG 2020 13:39

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:53:18

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	18 AUG 2020 23:43
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	19 AUG 2020 16:28
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3032108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

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)	9 SEP 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 15:17
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

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)	9 SEP 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 17:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	87 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3032108

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	9 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)	

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 16:38 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 16:38

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

US3032108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	16:06 (24 HR)
Collection date and time (derived)	9 SEP 2020 16:06

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:00	9 SEP 2020 16:00
Nasopharyngeal Swab 2	No		

US3032108

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 17:10

PC Open Date & Time

09 SEP 2020 16:58

PC Close Date & Time

09 SEP 2020 19:28

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 09 SEP 2020 20:23

PC Close Date & Time 10 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 05:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 12:16

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 07:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 15:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

97.4 °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

14 SEP 2020 12:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

15 SEP 2020 16:54

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:10

PC Open Date & Time

09 SEP 2020 16:58

PC Close Date & Time

09 SEP 2020 19:28

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 20:23

PC Close Date & Time

10 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

11 SEP 2020 05:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

11 SEP 2020 12:16

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

13 SEP 2020 07:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

13 SEP 2020 15:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

14 SEP 2020 12:04

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

15 SEP 2020 16:54

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 17:10
PC Open Date & Time	09 SEP 2020 16:58
PC Close Date & Time	09 SEP 2020 19:28

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 20:23

PC Close Date & Time

10 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

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 ☒

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 05:19
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 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

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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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

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 ☒

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 07:35
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 15:10
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:04
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

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 ☒

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 16:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time stamp

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 10

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 16 SEP 2020 12:00

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3032108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 21:50:02

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 01 Oct 2020 21:50:02

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Nov 2020 16:10:55

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:20:38

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 15:20:38

Generated On: 09 Jun 2021 14:53:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:20:38

Generated On: 09 Jun 2021 14:53:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 OCT 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 14:40
Temperature (xxx.x)	37.0 C
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032108

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 15:20:38

Generated On: 09 Jun 2021 14:53:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3032108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 15:20:38

Generated On: 09 Jun 2021 14:53:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 OCT 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

5 OCT 2020 14:50

US3032108

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:20:38

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 <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	09 OCT 2020 09:49:56
Patient Cloud Open Date & Time	05 OCT 2020 00:01
Patient Cloud Close Date & Time	09 OCT 2020 23:59

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

13 OCT 2020 12:23:30

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 04:13:27

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 NOV 2020 12:53:46
Patient Cloud Open Date & Time	02 NOV 2020 00:01
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 11:03:02

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 106
Have 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"/>

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 20:29:11

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 <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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 124

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

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 10:31:28

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

21 DEC 2020 10:27:39

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 JAN 2021 13:02:37
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 159

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 166

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

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 187

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

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

01 MAR 2021 10:35:17

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

12 MAR 2021 09:23:43

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 236

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

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 09:11:09

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 250

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

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐
Yes ☐

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐ Yes ☐

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐ Yes ☐

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐ Yes ☐

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 530

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

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

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

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

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

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

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 649

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

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

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

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

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

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

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Patient Cloud Open Date & Time	19 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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="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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Patient Cloud Open Date & Time	02 SEP 2022 00:01
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Patient Cloud Close Date & Time	06 SEP 2022 23:59
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US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3032108

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:53:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 10:35:02

US3032108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Nov 2020 23:34:45

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Nov 2020 23:34:45

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Dec 2020 20:07:01

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Dec 2020 20:07:01

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 30 Jan 2021 16:47:19

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 30 Jan 2021 16:47:19

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:21:00

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:21:00

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 15:21:01

Generated On: 09 Jun 2021 14:53:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

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) _____

US3032108

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 15:21:01

Generated On: 09 Jun 2021 14:53:18

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.

US3032108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 15:21:00

Generated On: 09 Jun 2021 14:53:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 MAR 2021

Collection time (00:00-23:59)

14:52 (24 HR)

Collection date and time (derived)

8 MAR 2021 14:52

US3032108

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:21:00

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032108

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:53:18

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"/>

US3032108

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:53:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3032108

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

Form: Visit Date

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

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

Visit date (dd MMM yyyy)	2 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	UNBLND_DECIDE
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US3032108

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:10:46

Generated On: 09 Jun 2021 14:53:18

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

US3032108

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

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

US3032108

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 MAR 2021
Time of assessment (00:00-23:59)	18:10 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 18:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3032108

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 MAR 2021
Time of assessment (00:00-23:59)	19:01 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 19:01
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3032108

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

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 MAR 2021

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

US3032108

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

Form: Pregnancy Test

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 2 MAR 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3032108

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

Form: Exposure

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 MAR 2021

What was the treatment time? (00:00-23:59) 18:29 (24 HR)

Treatment Date and Time (derived) 2 MAR 2021 18:29

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

US3032108

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

17:53 (24 HR)

Collection date and time (derived)

2 MAR 2021 17:53

US3032108

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00 - 23:59)	18:00
Collection Date and Time (derived)	2 MAR 2021 18:00

US3032108

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

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:01:54

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:10:46

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:10:46

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

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)	5 APR 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 11:40
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	5 APR 2021
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 12:43
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3032108

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 APR 2021

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

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	5 APR 2021
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)	

US3032108

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 5 APR 2021

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

Treatment Date and Time (derived) 5 APR 2021 12:12

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

US3032108

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:55

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 15:26:19

Generated On: 09 Jun 2021 14:53:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032108

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 15:26:19

Generated On: 09 Jun 2021 14:53:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032108

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3032108

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

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.

US3032108

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 20 Nov 2020 16:10:55

Generated On: 09 Jun 2021 14:53:18

Visit Date	19 AUG 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Data signed: (b) (4) 20 Nov 2020 16:10:55

Generated On: 09 Jun 2021 14:53:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:17 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 09:17
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Physical Examination

Data signed: (b) (4) 20 Nov 2020 16:10:55

Generated On: 09 Jun 2021 14:53:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

US3032108

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

AEID	
Adverse event	TENSION HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

AEID

Adverse event

ARTHRALGIA

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)

9 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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)	

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

AEID

Adverse event

MYALGIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

9 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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)	

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

AEID

Adverse event

ARTHRALGIA

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)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

AEID

Adverse event

MYALGIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☒

No ☐

Start date (dd MMM yyyy)

13 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)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

AEID

Adverse event

FATIGUE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 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)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 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)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

AEID	USA-US032-2021-MRNA-1273-P30 1000012
Adverse event	TOOTH DECAY ON RIGHT SIDE OF THE MOUTH.
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	25 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

SUBJECT WENT TO DENTIST FOR A ROTTEN TOOTH ON THE RIGHT SIDE OF THE MOUTH. THE TOOTH WAS PULLED AT THAT TIME. THEN SUBJECT DEVELOPED SEVERE PAIN AND SWELLING. SUBJECT WENT TO THE ER. THE ER THEN SENT SUBJECT HOME AND TOLD HER TO GO TO THE DENTIST. WHEN AT THE DENTIST THE DENTIST THEN SAID TO GO TO ER. AT THAT TIME THE ER DID A CT SCAN AND REALIZED THAT THE INFECTION WAS SEVERE AND REQUIRED TREATMENT THAT MEET INPATIENT CRITERIA. THEY DID A BALLOON SINUPLASTY TO HELP WITH THE INFECTION AND DRAINAGE. SUBJECT WAS DISCHARGED IN STABLE CONDITION ON 25 APR 2021. SUBJECT HAS SIGNED A MEDICAL RELEASE FORM AT THIS TIME. WILL UPDATE SAE AS MORE INFORMATION BECOMES AVAILABLE.

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

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

AEID

Adverse event

ACUTE RIGHT MAXILLARY
SINUSITIS

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)

19 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 16:55:45

Generated On: 09 Jun 2021 14:53:18

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

Yes ☒

No ☐

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

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

Name of Medication	ALBUTEROL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	90
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

	Respiratory (Inhalation)	<input checked="" 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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

Name of Medication EXCEDRIN MIGRAINE
(ACETAMINOPHEN, ASPIRIN,
CAFFEINE)

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 250/250/65

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 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"/>

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

Name of Medication FIORINAL (ASPIRIN,
BUTALBITAL, CAFFEINE)

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 325/50/40

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

If dose unit is Other, specify

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

If frequency is Other, specify EVERY 4 HOURS AS NEEDED

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)

Generated On: 09 Jun 2021 14:53:18

	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)		24 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

Name of Medication	HYDROCODONE/ACETAMINOP HEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACUTE RIGHT MAXILLARY SINUSITIS
Dose per administration	3/325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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)

Generated On: 09 Jun 2021 14:53:18

Name of Medication	CLINDAMYCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACUTE RIGHT MAXILLARY SINUSITIS
Dose per administration	300
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:53:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 14:53:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 APR 2021	TOOTH EXTRACTION	Adverse Event	
22 APR 2021	CT SCAN	Adverse Event	
23 APR 2021	BALLOON SINUPLASTY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:53:18

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

US3032108

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:53:18

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 ☐

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

SAEID	USA-US032-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

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Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:18

SAEID	USA-US032-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	03/MAY/2021 05:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:18

SAEID	USA-US032-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	03/MAY/2021 11:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3032108 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032108

Form: Participant Creation

Generated On: 09 Jun 2021 14:53:18

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:34:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'US3032108'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	05 Aug 2020 23:14:18

US3032108

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	06 Aug 2020 00:31:23

US3032108

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	05 Aug 2020 23:14:19

US3032108

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Clinic (Clinic)'	Linden DeBoer (b) (4)	06 Aug 2020 00:31:23

US3032108

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'SCRN'	System	06 Aug 2020 00:31:23

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered (b) (6) 1991'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	05 Aug 2020 23:14:20

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '29'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'YEARS'	System	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '29'	System	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Female (F)'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'I'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:14

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '05 Aug 2020'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'Aug 2020'	System	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '2020'	System	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Amendment 1 (1)'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Linden DeBoer (b) (4)	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	06 Aug 2020 00:32:32
	(b) (4)	

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:32

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	05 Aug 2020 23:14:19

US3032108

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'I'	System	06 Aug 2020 00:32:37

US3032108

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:53:18

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:37:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	06 Aug 2020 00:32:37

US3032108

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:53:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:38:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Aug 2020 18:30:53

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:33:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:33:27
Data point term sent to Coder	System	19 Aug 2020 18:31:59
User entered 'penicillin allergy'	Kelsey Kelley (b) (4)	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'un UNK 2015'	Kelsey Kelley (b) (4)	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:34
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	14 Oct 2020 13:51:24
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'Jan 2015'	System	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '2015'	System	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	19 Aug 2020 18:31:20

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:33:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:33:26
Data point term sent to Coder	System	19 Aug 2020 18:31:59
User entered 'asthma'	Kelsey Kelley (b) (4)	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'un UNK 2005'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'Jan 2005'	System	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '2005'	System	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	19 Aug 2020 18:31:31

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Chronic headaches - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:33:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:33:26
Data point term sent to Coder	System	19 Aug 2020 18:31:59
User entered 'chronic headache'	Kelsey Kelley (b) (4)	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'un UNK 2009'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Kelsey Kelley (b) (4)	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'Jan 2009'	System	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '2009'	System	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	19 Aug 2020 18:31:50

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '18:07'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '5 Aug 2020 18:07'	System	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '157.4' cm	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10
DataPoint set to visible.	(b) (4) System	06 Aug 2020 00:32:37

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '48.5' kg	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10
DataPoint set to visible.	(b) (4) System	06 Aug 2020 00:32:37

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
Amendment Manager: User entered '19.57638'	System	16 Sep 2020 23:44:52
User entered '19.6'	System	06 Aug 2020 01:02:10
DataPoint set to visible.	System	06 Aug 2020 00:32:37

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'kg/m2'	System	06 Aug 2020 01:02:10
DataPoint set to visible.	System	06 Aug 2020 00:32:37

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' (Site from DM).	(b) (4)	01 Oct 2020 04:51:17
Query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:15
Signature has been broken.	(b) (4)	30 Sep 2020 12:59:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
User opened query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:32:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '36.8' C	Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10
	(b) (4)	

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:51:19
Query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:59:20
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:59:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:59:10
User opened query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:33:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:55:46
User entered '68'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'bpm'	System	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered '14'	Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'breaths/min'	System	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered '101'	Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'mmHg'	System	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Signature has been broken.	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:59:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '68'	Kelsey Kelley (b) (4)	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'mmHg'	System	06 Aug 2020 01:02:10

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15

US3032108

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15

US3032108

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:17

US3032108

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 10:01:10
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:52:35
User entered '5 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:02:17

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:18

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:16

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:30

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:30

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Urine (URINE)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:30

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:30

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:23
User closed query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4)	27 Oct 2020 09:02:04
Query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	
Signature has been broken.	Linden DeBoer (b) (4)	23 Oct 2020 16:29:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 16:29:32
User opened query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	Linden DeBoer (b) (4)	23 Oct 2020 13:33:04
User signature succeeded.	(b) (4), (b) (6)	
User entered empty.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:30
	(b) (4)	

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:30

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:30

US3032108

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	06 Aug 2020 01:00:30

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[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	(b) (4)	06 Aug 2020 01:03:40
User entered '1' reason for change: Data Entry Error	System	06 Aug 2020 01:03:40
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	Kelsey Kelley (b) (4)	06 Aug 2020 01:03:40
User entered '0'	(b) (4)	06 Aug 2020 00:59:28
	System	06 Aug 2020 00:59:28
	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:18

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:18

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:18

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:28

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:43

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:43

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 00:59:43

US3032108

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'VISIT1'	System	06 Aug 2020 00:59:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	05 Aug 2020 23:49:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:18

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:24:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:24:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 23:49:15
User entered '101356' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:49:15
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	05 Aug 2020 23:49:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:18

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)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:01:10

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Folder: Visit 1 Day 1

Form: Randomization

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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)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:01:10

US3032108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:18

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:01:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:18

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:01:10

US3032108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:01:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:51:38
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:45
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:40
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:32:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:55:46
User entered '157.4' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Sep 2020 12:57:40
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:57:40
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered '48.5' kg	Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:51:38
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:45
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:40
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:32:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:55:46
User entered '157.4' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Sep 2020 12:57:40
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:57:40
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered '48.5' kg	Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '18:07'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '5 Aug 2020 18:07'	System	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '68'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'bpm'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'breaths/min'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '101'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'mmHg'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '68'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'mmHg'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:51:38
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:45
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	30 Sep 2020 12:57:40
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:32:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:55:46
User entered '157.4' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Sep 2020 12:57:40
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	30 Sep 2020 12:57:40
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered '48.5' kg	Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03
	(b) (4)	

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:24:35
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	13 Aug 2020 23:25:39
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		06 Aug 2020 01:15:03
User entered '19:45'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '5 Aug 2020 19:45'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '70'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'bpm'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'breaths/min'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User closed query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:31:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
Query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' answered with 'NCS' (Site from DM).	(b) (4)	
Query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' answered with 'NCS' (Site from DM).	Kelsey Kelley (b) (4)	28 Sep 2020 13:25:44
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 03:46:13
User opened query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:18:27
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Investigator determined as normal variant for this patient. ' (Site from System).	Kelsey Kelley (b) (4)	21 Sep 2020 15:02:21
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:44:51
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Aug 2020 01:15:03
User entered '77'	Kelsey Kelley (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'mmHg'	System	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User closed query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:31:14
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:55:46
Query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' answered with 'NCS' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	28 Sep 2020 13:25:48
User opened query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:18:38
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 07:18:30
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Investigator determined as normal variant for this patient. ' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 15:02:25
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:44:52
User entered '59'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:15:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'mmHg'	System	06 Aug 2020 01:15:03

US3032108

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:29

US3032108

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:02:29

US3032108

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:23
User closed query 'Per CDM, re-query: Per CCGs, 'Was the pregnancy test performed?' is to be recorded as "No" at Visit 1 Day 1 when it is on the same day as Screening. This field should not remain empty. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 09:58:32
Query 'Per CDM, re-query: Per CCGs, 'Was the pregnancy test performed?' is to be recorded as "No" at Visit 1 Day 1 when it is on the same day as Screening. This field should not remain empty. Please update accordingly. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:32:53
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	27 Oct 2020 13:32:46
User opened query 'Per CDM, re-query: Per CCGs, 'Was the pregnancy test performed?' is to be recorded as "No" at Visit 1 Day 1 when it is on the same day as Screening. This field should not remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:01:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:01:37
User closed query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:01:35
Query 'Data is required. Please complete.' answered with 'data removed per DM request' (Site from System).	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:17

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

Was the pregnancy test performed?

Audit	User	Time (GMT)
Query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' answered with 'data removed per DM request' (Site from DM). User opened query 'Data is required. Please complete.' (Site from System). Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:13
	System	23 Oct 2020 12:55:03
	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:03
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:03
User opened query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Keith Vrbicky (b) (4) (b) (4)	23 Oct 2020 11:46:25 28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:00:43

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:23
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 12:55:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 12:55:03
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered '5 Aug 2020'	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:43
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:23
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 12:55:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 12:55:03
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:43
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:23
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 12:55:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 12:55:03
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:00:43
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:23
User closed query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 09:58:33
Query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4)	27 Oct 2020 13:32:57
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	27 Oct 2020 13:32:46
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	27 Oct 2020 13:32:46
User opened query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:01:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:43

US3032108

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:43

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:00:43

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered empty.	System	06 Aug 2020 01:00:43

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Linden DeBoer (b) (4)	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Linden DeBoer (b) (4)	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '05 Aug 2020'	Linden DeBoer (b) (4)	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '19:12'	Linden DeBoer (b) (4)	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '05 Aug 2020 19:12'	System	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Left Arm (LEFT ARM)'	Linden DeBoer (b) (4)	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'ONCE'	System	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 00:33:10

US3032108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:04:17

US3032108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:04:17

US3032108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '18:32'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:04:17

US3032108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '5 Aug 2020 18:32'	System	06 Aug 2020 01:04:17

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '18:21'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '5 Aug 2020 18:21'	System	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered empty.	System	06 Aug 2020 01:08:21

US3032108

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:08:24

US3032108

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	06 Aug 2020 01:08:24

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:44:59', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '33e8dabf-d0d9-46ca-bf16-d666160d74b0'	System	06 Aug 2020 00:45:16
User entered 'Yes (Y)'	System	06 Aug 2020 00:45:16

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:04', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '33e8dabf-d0d9-46ca-bf16-d666160d74b0'	System	06 Aug 2020 00:45:16
User entered '98.4'	System	06 Aug 2020 00:45:16

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:09', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '33e8dabf-d0d9-46ca-bf16-d666160d74b0'	System	06 Aug 2020 00:45:16
User entered 'No (N)'	System	06 Aug 2020 00:45:16

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:13', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '33e8dabf-d0d9-46ca-bf16-d666160d74b0'	System	06 Aug 2020 00:45:16
User entered '05 Aug 2020 19:45'	System	06 Aug 2020 00:45:16

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 19:32'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 22:02'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:21:51', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '830f05f6-24e4-4ea0-aa11-5f80753dd191'	System	06 Aug 2020 09:22:05
User entered 'Yes (Y)'	System	06 Aug 2020 09:22:05

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:21:56', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '830f05f6-24e4-4ea0-aa11-5f80753dd191'	System	06 Aug 2020 09:22:05
User entered '97.3'	System	06 Aug 2020 09:22:05

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:21:59', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '830f05f6-24e4-4ea0-aa11-5f80753dd191'	System	06 Aug 2020 09:22:05
User entered 'No (N)'	System	06 Aug 2020 09:22:05

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:02', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '830f05f6-24e4-4ea0-aa11-5f80753dd191'	System	06 Aug 2020 09:22:05
User entered '06 Aug 2020 04:22'	System	06 Aug 2020 09:22:05

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 22:57'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 2'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:20', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c7ebd756-306b-4d1a-998d-58b94bc73990'	System	06 Aug 2020 17:06:34
User entered 'Yes (Y)'	System	06 Aug 2020 17:06:34

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:26', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c7ebd756-306b-4d1a-998d-58b94bc73990' User entered '98.3'	System	06 Aug 2020 17:06:34
	System	06 Aug 2020 17:06:34

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:29', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c7ebd756-306b-4d1a-998d-58b94bc73990'	System	06 Aug 2020 17:06:34
User entered 'No (N)'	System	06 Aug 2020 17:06:34

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c7ebd756-306b-4d1a-998d-58b94bc73990'	System	06 Aug 2020 17:06:34
User entered '06 Aug 2020 12:06'	System	06 Aug 2020 17:06:34

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 3'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:02', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9521b4da-aa27-46c4-a221-460b54dd2ec8'	System	07 Aug 2020 20:57:18
User entered 'Yes (Y)'	System	07 Aug 2020 20:57:18

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:07', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9521b4da-aa27-46c4-a221-460b54dd2ec8' User entered '97.4'	System	07 Aug 2020 20:57:18
	System	07 Aug 2020 20:57:18

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:09', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9521b4da-aa27-46c4-a221-460b54dd2ec8'	System	07 Aug 2020 20:57:18
User entered 'No (N)'	System	07 Aug 2020 20:57:18

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:12', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9521b4da-aa27-46c4-a221-460b54dd2ec8'	System	07 Aug 2020 20:57:18
User entered '07 Aug 2020 15:57'	System	07 Aug 2020 20:57:18

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 4'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb15d609-bf82-429e-bac3-a77a3c55641a'	System	09 Aug 2020 05:32:28
User entered 'Yes (Y)'	System	09 Aug 2020 05:32:28

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:18', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb15d609-bf82-429e-bac3-a77a3c55641a'	System	09 Aug 2020 05:32:28
User entered '97.3'	System	09 Aug 2020 05:32:28

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:20', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb15d609-bf82-429e-bac3-a77a3c55641a'	System	09 Aug 2020 05:32:28
User entered 'No (N)'	System	09 Aug 2020 05:32:28

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:22', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb15d609-bf82-429e-bac3-a77a3c55641a'	System	09 Aug 2020 05:32:28
User entered '09 Aug 2020 00:32'	System	09 Aug 2020 05:32:28

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 5'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:21', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d1a369e-fb13-4647-ad63-d8d5b984c586'	System	10 Aug 2020 01:55:35
User entered 'Yes (Y)'	System	10 Aug 2020 01:55:35

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:26', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d1a369e-fb13-4647-ad63-d8d5b984c586'	System	10 Aug 2020 01:55:35
User entered '97.7'	System	10 Aug 2020 01:55:35

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:29', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d1a369e-fb13-4647-ad63-d8d5b984c586'	System	10 Aug 2020 01:55:35
User entered 'No (N)'	System	10 Aug 2020 01:55:35

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d1a369e-fb13-4647-ad63-d8d5b984c586'	System	10 Aug 2020 01:55:35
User entered '09 Aug 2020 20:55'	System	10 Aug 2020 01:55:35

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 6'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:36', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6311e22a-19ca-4b45-a9d3-efce65f0f69a'	System	10 Aug 2020 17:32:51
User entered 'Yes (Y)'	System	10 Aug 2020 17:32:51

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6311e22a-19ca-4b45-a9d3-efce65f0f69a' User entered '97.7'	System	10 Aug 2020 17:32:51
	System	10 Aug 2020 17:32:51

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:42', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6311e22a-19ca-4b45-a9d3-efce65f0f69a'	System	10 Aug 2020 17:32:51
User entered 'No (N)'	System	10 Aug 2020 17:32:51

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:46', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6311e22a-19ca-4b45-a9d3-efce65f0f69a' User entered '10 Aug 2020 12:32'	System	10 Aug 2020 17:32:51
	System	10 Aug 2020 17:32:51

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 7'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:20:52', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d4f32e4-b83a-4048-8c32-9f4ed94fa354'	System	11 Aug 2020 17:21:08
User entered 'Yes (Y)'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:20:55', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d4f32e4-b83a-4048-8c32-9f4ed94fa354'	System	11 Aug 2020 17:21:08
User entered '98.9'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:20:58', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d4f32e4-b83a-4048-8c32-9f4ed94fa354'	System	11 Aug 2020 17:21:08
User entered 'Yes (Y)'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
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 'Con med page updated ' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 06:41:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Kelsey Kelley (b) (4)	16 Sep 2020 14:19:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:03', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d4f32e4-b83a-4048-8c32-9f4ed94fa354'	System	11 Aug 2020 17:21:08
User entered '1'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:03', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d4f32e4-b83a-4048-8c32-9f4ed94fa354'	System	11 Aug 2020 17:21:08
User entered '0'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:05', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0d4f32e4-b83a-4048-8c32-9f4ed94fa354'	System	11 Aug 2020 17:21:08
User entered '11 Aug 2020 12:21'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 8'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:23', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8617f0c5-eec9-4f42-baf2-453b83b7ea63'	System	12 Aug 2020 17:02:57
User entered 'Yes (Y)'	System	12 Aug 2020 17:02:57

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8617f0c5-eec9-4f42-baf2-453b83b7ea63' User entered '97.7'	System	12 Aug 2020 17:02:57
	System	12 Aug 2020 17:02:57

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:32', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8617f0c5-eec9-4f42-baf2-453b83b7ea63'	System	12 Aug 2020 17:02:57
User entered 'No (N)'	System	12 Aug 2020 17:02:57

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:34', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8617f0c5-ee9-4f42-baf2-453b83b7ea63'	System	12 Aug 2020 17:02:57
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 17:02:57

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:21', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '23d24ec7-4cac-4beb-ba37-64aa784026de'	System	06 Aug 2020 00:45:50
User entered 'None (1)'	System	06 Aug 2020 00:45:50

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '23d24ec7-4cac-4beb-ba37-64aa784026de'	System	06 Aug 2020 00:45:50
User entered 'No (N)'	System	06 Aug 2020 00:45:50

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '23d24ec7-4cac-4beb-ba37-64aa784026de'	System	06 Aug 2020 00:45:50
User entered 'No (N)'	System	06 Aug 2020 00:45:50

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:43', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '23d24ec7-4cac-4beb-ba37-64aa784026de'	System	06 Aug 2020 00:45:50
User entered 'None (1)'	System	06 Aug 2020 00:45:50

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:47', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '23d24ec7-4cac-4beb-ba37-64aa784026de'	System	06 Aug 2020 00:45:50
User entered '05 Aug 2020 19:45'	System	06 Aug 2020 00:45:50

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 19:32'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 22:02'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:06', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '566cd042-a978-4423-bcd6-3e3ae16a277d'	System	06 Aug 2020 09:22:23
User entered 'None (1)'	System	06 Aug 2020 09:22:23

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:09', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '566cd042-a978-4423-bcd6-3e3ae16a277d'	System	06 Aug 2020 09:22:23
User entered 'No (N)'	System	06 Aug 2020 09:22:23

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '566cd042-a978-4423-bcd6-3e3ae16a277d'	System	06 Aug 2020 09:22:23
User entered 'No (N)'	System	06 Aug 2020 09:22:23

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '566cd042-a978-4423-bcd6-3e3ae16a277d'	System	06 Aug 2020 09:22:23
User entered 'None (1)'	System	06 Aug 2020 09:22:23

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:19', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '566cd042-a978-4423-bcd6-3e3ae16a277d'	System	06 Aug 2020 09:22:23
User entered '06 Aug 2020 04:22'	System	06 Aug 2020 09:22:23

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 22:57'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 2'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a037203c-73c6-4fe0-8eae-7a09f04ee720'	System	06 Aug 2020 17:06:48
User entered 'None (1)'	System	06 Aug 2020 17:06:48

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a037203c-73c6-4fe0-8eae-7a09f04ee720'	System	06 Aug 2020 17:06:48
User entered 'No (N)'	System	06 Aug 2020 17:06:48

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:41', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a037203c-73c6-4fe0-8eae-7a09f04ee720'	System	06 Aug 2020 17:06:48
User entered 'No (N)'	System	06 Aug 2020 17:06:48

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:43', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a037203c-73c6-4fe0-8eae-7a09f04ee720'	System	06 Aug 2020 17:06:48
User entered 'None (1)'	System	06 Aug 2020 17:06:48

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:46', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a037203c-73c6-4fe0-8eae-7a09f04ee720'	System	06 Aug 2020 17:06:48
User entered '06 Aug 2020 12:06'	System	06 Aug 2020 17:06:48

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 3'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:15', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4f25f9f5-641a-4473-92bd-bf3c826db5bc'	System	07 Aug 2020 20:57:29
User entered 'None (1)'	System	07 Aug 2020 20:57:29

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4f25f9f5-641a-4473-92bd-bf3c826db5bc'	System	07 Aug 2020 20:57:29
User entered 'No (N)'	System	07 Aug 2020 20:57:29

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:19', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4f25f9f5-641a-4473-92bd-bf3c826db5bc'	System	07 Aug 2020 20:57:29
User entered 'No (N)'	System	07 Aug 2020 20:57:29

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:21', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4f25f9f5-641a-4473-92bd-bf3c826db5bc'	System	07 Aug 2020 20:57:29
User entered 'None (1)'	System	07 Aug 2020 20:57:29

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:23', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4f25f9f5-641a-4473-92bd-bf3c826db5bc'	System	07 Aug 2020 20:57:29
User entered '07 Aug 2020 15:57'	System	07 Aug 2020 20:57:29

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 4'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:26', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f16ee9f1-7970-460f-9083-f28606b7d5fe'	System	09 Aug 2020 05:32:38
User entered 'None (1)'	System	09 Aug 2020 05:32:38

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f16ee9f1-7970-460f-9083-f28606b7d5fe'	System	09 Aug 2020 05:32:38
User entered 'No (N)'	System	09 Aug 2020 05:32:38

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:29', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f16ee9f1-7970-460f-9083-f28606b7d5fe'	System	09 Aug 2020 05:32:38
User entered 'No (N)'	System	09 Aug 2020 05:32:38

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f16ee9f1-7970-460f-9083-f28606b7d5fe'	System	09 Aug 2020 05:32:38
User entered 'None (1)'	System	09 Aug 2020 05:32:38

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:32:33', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f16ee9f1-7970-460f-9083-f28606b7d5fe'	System	09 Aug 2020 05:32:38
User entered '09 Aug 2020 00:32'	System	09 Aug 2020 05:32:38

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 5'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:34', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a4df635b-9292-4c96-b586-0d3c3f6dd8a3'	System	10 Aug 2020 01:55:43
User entered 'None (1)'	System	10 Aug 2020 01:55:43

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:36', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a4df635b-9292-4c96-b586-0d3c3f6dd8a3'	System	10 Aug 2020 01:55:43
User entered 'No (N)'	System	10 Aug 2020 01:55:43

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a4df635b-9292-4c96-b586-0d3c3f6dd8a3'	System	10 Aug 2020 01:55:43
User entered 'No (N)'	System	10 Aug 2020 01:55:43

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a4df635b-9292-4c96-b586-0d3c3f6dd8a3'	System	10 Aug 2020 01:55:43
User entered 'None (1)'	System	10 Aug 2020 01:55:43

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:41', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a4df635b-9292-4c96-b586-0d3c3f6dd8a3'	System	10 Aug 2020 01:55:43
User entered '09 Aug 2020 20:55'	System	10 Aug 2020 01:55:43

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 6'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:50', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '336973ee-8247-4491-858f-2fc81fbc2012'	System	10 Aug 2020 17:33:01
User entered 'None (1)'	System	10 Aug 2020 17:33:01

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:52', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '336973ee-8247-4491-858f-2fc81fbc2012'	System	10 Aug 2020 17:33:01
User entered 'No (N)'	System	10 Aug 2020 17:33:01

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:54', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '336973ee-8247-4491-858f-2fc81fbc2012'	System	10 Aug 2020 17:33:01
User entered 'No (N)'	System	10 Aug 2020 17:33:01

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:56', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '336973ee-8247-4491-858f-2fc81fbc2012'	System	10 Aug 2020 17:33:01
User entered 'None (1)'	System	10 Aug 2020 17:33:01

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:32:58', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '336973ee-8247-4491-858f-2fc81fbc2012'	System	10 Aug 2020 17:33:01
User entered '10 Aug 2020 12:32'	System	10 Aug 2020 17:33:01

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 7'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:10', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ddc11534-9f1b-44f9-b351-0164b3e1be6d'	System	11 Aug 2020 17:21:21
User entered 'None (1)'	System	11 Aug 2020 17:21:21

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:12', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ddc11534-9f1b-44f9-b351-0164b3e1be6d'	System	11 Aug 2020 17:21:21
User entered 'No (N)'	System	11 Aug 2020 17:21:21

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ddc11534-9f1b-44f9-b351-0164b3e1be6d'	System	11 Aug 2020 17:21:21
User entered 'No (N)'	System	11 Aug 2020 17:21:21

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:16', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ddc11534-9f1b-44f9-b351-0164b3e1be6d'	System	11 Aug 2020 17:21:21
User entered 'None (1)'	System	11 Aug 2020 17:21:21

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:18', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ddc11534-9f1b-44f9-b351-0164b3e1be6d'	System	11 Aug 2020 17:21:21
User entered '11 Aug 2020 12:21'	System	11 Aug 2020 17:21:21

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:53', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered 'None (0)'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:45:58', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered 'None (0)'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:46:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered 'None (0)'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:46:03', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered 'None (0)'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:46:05', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered 'None (0)'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:46:10', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered 'None (0)'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:46:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered 'No (N)'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-05T19:46:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9caf9eae-761c-47ad-811c-7e63972f09cf'	System	06 Aug 2020 00:46:19
User entered '05 Aug 2020 19:46'	System	06 Aug 2020 00:46:19

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 19:32'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 22:02'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:23', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered 'None (0)'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:25', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered 'None (0)'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered 'None (0)'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered 'None (0)'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:32', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered 'None (0)'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:35', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered 'None (0)'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:38', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered 'No (N)'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T04:22:41', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '58bfbcc-492d-4f36-af5c-8faf481f9208'	System	06 Aug 2020 09:22:44
User entered '06 Aug 2020 04:22'	System	06 Aug 2020 09:22:44

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '05 Aug 2020 22:57'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 2'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:50', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered 'None (0)'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:53', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered 'None (0)'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:06:57', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered 'None (0)'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:07:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered 'None (0)'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:07:02', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered 'None (0)'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:07:06', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered 'No interference with activity (1)'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:07:08', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered 'No (N)'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-06T12:07:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'df47af95-583e-4f46-86ce-91c7422d0331'	System	06 Aug 2020 17:07:13
User entered '06 Aug 2020 12:07'	System	06 Aug 2020 17:07:13

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 3'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:26', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered 'None (0)'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered 'None (0)'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered 'None (0)'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered 'None (0)'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:34', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered 'None (0)'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:35', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered 'None (0)'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered 'No (N)'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-07T15:57:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4101c82e-fd9e-4a41-9008-bda8fa703cbf'	System	07 Aug 2020 20:57:43
User entered '07 Aug 2020 15:57'	System	07 Aug 2020 20:57:43

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 4'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:09', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:12', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered 'None (0)'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:19', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered 'No interference with activity (1)'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:22', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered 'None (0)'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:29', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered 'None (0)'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:34', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered 'No (N)'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T00:33:36', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2a9a5820-bcaa-40cb-9e90-7194a7c846b0'	System	09 Aug 2020 05:33:41
User entered '09 Aug 2020 00:33'	System	09 Aug 2020 05:33:41

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 5'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:48', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered 'No interference with activity (1)'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:51', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered 'None (0)'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:55', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered 'No interference with activity (1)'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:57', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered 'None (0)'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:55:58', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered 'None (0)'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:56:01', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered 'No (N)'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-09T20:56:03', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd47675d7-6a09-41de-8a23-1f9f6456ce0f'	System	10 Aug 2020 01:56:06
User entered '09 Aug 2020 20:56'	System	10 Aug 2020 01:56:06

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 6'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:02', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered 'No interference with activity (1)'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:05', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered 'None (0)'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered 'No interference with activity (1)'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered 'Some interference with activity (2)'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:16', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered 'None (0)'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered 'None (0)'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:22', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered 'No (N)'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-10T12:33:24', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '2794d5fe-515d-4940-9658-9d5aea344bca'	System	10 Aug 2020 17:33:26
User entered '10 Aug 2020 12:33'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 7'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered 'None (0)'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:35', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered 'No interference with activity (1)'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered 'No interference with activity (1)'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:43', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered 'None (0)'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:49', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered 'No (N)'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-11T12:21:52', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '45d5c1de-6390-4b2f-b4ec-5d47b1a6c615'	System	11 Aug 2020 17:21:54
User entered '11 Aug 2020 12:21'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	10 Aug 2020 17:33:26
User entered 'Day 8'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f8ef44f9-3fd5-42f7-aa74-34cdfb81b793'	System	12 Aug 2020 17:02:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	12 Aug 2020 17:02:55

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:19', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f8ef44f9-3fd5-42f7-aa74-34cdfb81b793'	System	12 Aug 2020 17:02:55
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 17:02:55

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	11 Aug 2020 17:21:54
User entered 'Day 9'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:17:46', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '1eb3bf19-0217-4b15-9405-203ac689528e'	System	13 Aug 2020 17:17:54
User entered 'No interference with activity (1)'	System	13 Aug 2020 17:17:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:17:48', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '1eb3bf19-0217-4b15-9405-203ac689528e'	System	13 Aug 2020 17:17:54
User entered '13 Aug 2020 12:17'	System	13 Aug 2020 17:17:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	12 Aug 2020 17:02:55
User entered 'Day 10'	System	12 Aug 2020 17:02:55

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-14T13:36:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fde00a03-079c-4c86-a177-4891fdb6876f'	System	14 Aug 2020 18:36:35
User entered 'No interference with activity (1)'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-14T13:36:32', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fde00a03-079c-4c86-a177-4891fdb6876f'	System	14 Aug 2020 18:36:35
User entered '14 Aug 2020 13:36'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:02:55

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:02:55

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	13 Aug 2020 17:17:54
User entered 'Day 11'	System	13 Aug 2020 17:17:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-15T18:04:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '183674fb-6bb8-4092-8ce5-58511fc8b23c'	System	15 Aug 2020 23:04:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-15T18:04:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '183674fb-6bb8-4092-8ce5-58511fc8b23c'	System	15 Aug 2020 23:04:42
User entered '15 Aug 2020 18:04'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:17:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:17:54

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	14 Aug 2020 18:36:35
User entered 'Day 12'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-16T16:08:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7f605a16-a6fd-4c5b-805a-9adf40fe28ae'	System	16 Aug 2020 21:08:52
User entered 'No interference with activity (1)'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-16T16:08:49', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7f605a16-a6fd-4c5b-805a-9adf40fe28ae'	System	16 Aug 2020 21:08:52
User entered '16 Aug 2020 16:08'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Aug 2020 23:04:42
User entered 'Day 13'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-17T13:39:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '66abf24c-6cc0-4a3a-87d3-51d8b8bef1cd'	System	17 Aug 2020 18:39:42
User entered 'No interference with activity (1)'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-17T13:39:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '66abf24c-6cc0-4a3a-87d3-51d8b8bef1cd'	System	17 Aug 2020 18:39:42
User entered '17 Aug 2020 13:39'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	16 Aug 2020 21:08:52
User entered 'Day 14'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-18T23:43:06', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '97bc9ce5-5041-43b9-b7d6-8896f99b7e02'	System	19 Aug 2020 04:43:13
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-18T23:43:08', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '97bc9ce5-5041-43b9-b7d6-8896f99b7e02'	System	19 Aug 2020 04:43:13
User entered '18 Aug 2020 23:43'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	17 Aug 2020 18:39:42
User entered 'Day 15'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-19T16:28:09', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a7db5dfb-9b56-4402-ae5d-a447efdd97eb'	System	19 Aug 2020 21:28:15
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		19 Aug 2020 21:28:15

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-19T16:28:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a7db5dfb-9b56-4402-ae5d-a447efdd97eb'	System	19 Aug 2020 21:28:15
User entered '19 Aug 2020 16:28'	System	19 Aug 2020 21:28:15

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	19 Aug 2020 04:43:13
User entered 'Day 16'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	19 Aug 2020 21:28:15
User entered 'Day 17'	System	19 Aug 2020 21:28:15

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:28:15

US3032108

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:28:15

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	10 Aug 2020 17:33:26
User entered 'Day 8'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '80b483e7-c5de-47be-921c-0e1ad034c611'	System	12 Aug 2020 17:02:20
User entered 'No interference with activity (1)'	System	12 Aug 2020 17:02:20

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:13', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '80b483e7-c5de-47be-921c-0e1ad034c611'	System	12 Aug 2020 17:02:20
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 17:02:20

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	11 Aug 2020 17:21:54
User entered 'Day 9'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:17:57', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a84967a5-d281-4f07-b17a-3204dae32259'	System	13 Aug 2020 17:18:05
User entered 'None (0)'	System	13 Aug 2020 17:18:05

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:18:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'a84967a5-d281-4f07-b17a-3204dae32259'	System	13 Aug 2020 17:18:05
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 17:18:05

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	10 Aug 2020 17:33:26
User entered 'Day 8'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:05', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '570bc941-7b63-48c7-9794-cf23b1d314cd'	System	12 Aug 2020 17:02:16
User entered 'No interference with activity (1)'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:07', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '570bc941-7b63-48c7-9794-cf23b1d314cd'	System	12 Aug 2020 17:02:16
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	11 Aug 2020 17:21:54
User entered 'Day 9'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:18:04', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '54810f37-8c98-476b-ac78-164e4cce55b2'	System	13 Aug 2020 17:18:10
User entered 'No interference with activity (1)'	System	13 Aug 2020 17:18:10

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:18:06', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '54810f37-8c98-476b-ac78-164e4cce55b2'	System	13 Aug 2020 17:18:10
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 17:18:10

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	12 Aug 2020 17:02:16
User entered 'Day 10'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-14T13:36:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '37a7571f-734e-4a2d-9179-e55b884e7d6c'	System	14 Aug 2020 18:36:42
User entered 'None (0)'	System	14 Aug 2020 18:36:42

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-14T13:36:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '37a7571f-734e-4a2d-9179-e55b884e7d6c'	System	14 Aug 2020 18:36:42
User entered '14 Aug 2020 13:36'	System	14 Aug 2020 18:36:42

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	11 Aug 2020 17:21:54
User entered 'Day 8'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:01:59', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '94502f28-b2a5-44ac-b596-73bbd8051950'	System	12 Aug 2020 17:02:13
User entered 'None (0)'	System	12 Aug 2020 17:02:13

US3032108

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:02:01', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '94502f28-b2a5-44ac-b596-73bbd8051950'	System	12 Aug 2020 17:02:13
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 17:02:13

US3032108

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:54

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	10 Aug 2020 17:33:26
User entered 'Day 8'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:01:48', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9f9fc088-7962-49a5-8ebc-db315ed8ad4d'	System	12 Aug 2020 17:02:02
User entered 'No (N)'	System	12 Aug 2020 17:02:02

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-12T12:01:50', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9f9fc088-7962-49a5-8ebc-db315ed8ad4d'	System	12 Aug 2020 17:02:02
User entered '12 Aug 2020 12:01'	System	12 Aug 2020 17:02:02

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:33:26

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 9'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:18:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd84f4075-f2bc-42d0-9375-a6b4a16e28d9'	System	13 Aug 2020 17:18:16
User entered 'No (N)'	System	13 Aug 2020 17:18:16

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-13T12:18:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd84f4075-f2bc-42d0-9375-a6b4a16e28d9'	System	13 Aug 2020 17:18:16
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 17:18:16

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	12 Aug 2020 17:02:16
User entered 'Day 10'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-14T13:36:42', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '62d32c44-83f1-4263-9e70-4b8fb84292a4'	System	14 Aug 2020 18:36:48
User entered 'No (N)'	System	14 Aug 2020 18:36:48

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-14T13:36:44', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '62d32c44-83f1-4263-9e70-4b8fb84292a4'	System	14 Aug 2020 18:36:48
User entered '14 Aug 2020 13:36'	System	14 Aug 2020 18:36:48

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:02:16

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	14 Aug 2020 18:36:35
User entered 'Day 12'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-16T16:08:38', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7cb7405d-a0f0-408f-9296-dedb62be1329'	System	16 Aug 2020 21:08:44
User entered 'No (N)'	System	16 Aug 2020 21:08:44

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-16T16:08:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7cb7405d-a0f0-408f-9296-dedb62be1329'	System	16 Aug 2020 21:08:44
User entered '16 Aug 2020 16:08'	System	16 Aug 2020 21:08:44

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 18:36:35

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Aug 2020 23:04:42
User entered 'Day 13'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-17T13:39:44', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '98bf88e3-85de-4789-ac66-89ac5eb2bd4e'	System	17 Aug 2020 18:39:49
User entered 'No (N)'	System	17 Aug 2020 18:39:49

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-17T13:39:47', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '98bf88e3-85de-4789-ac66-89ac5eb2bd4e'	System	17 Aug 2020 18:39:49
User entered '17 Aug 2020 13:39'	System	17 Aug 2020 18:39:49

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 23:04:42

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	16 Aug 2020 21:08:52
User entered 'Day 14'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-18T23:43:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7b9c780f-5647-486e-950a-5a7a779674a5'	System	19 Aug 2020 04:43:16
User entered 'No (N)'	System	19 Aug 2020 04:43:16

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-18T23:43:13', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7b9c780f-5647-486e-950a-5a7a779674a5'	System	19 Aug 2020 04:43:16
User entered '18 Aug 2020 23:43'	System	19 Aug 2020 04:43:16

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 21:08:52

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	17 Aug 2020 18:39:42
User entered 'Day 15'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-19T16:28:15', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd895be5a-3653-4565-a7e3-8181c41a1640'	System	19 Aug 2020 21:28:21
User entered 'Yes (Y)'	System	19 Aug 2020 21:28:21

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-08-19T16:28:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd895be5a-3653-4565-a7e3-8181c41a1640'	System	19 Aug 2020 21:28:21
User entered '19 Aug 2020 16:28'	System	19 Aug 2020 21:28:21

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:39:42

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	19 Aug 2020 04:43:13
User entered 'Day 16'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 04:43:13

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	19 Aug 2020 21:28:15
User entered 'Day 17'	System	19 Aug 2020 21:28:15

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:28:15

US3032108

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:28:15

US3032108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	21 Aug 2020 00:21:52

US3032108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '12 Aug 2020'	Samantha Wieseler (b) (4)	21 Aug 2020 00:21:52

US3032108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	21 Aug 2020 00:21:52

US3032108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Samantha Wieseler (b) (4)	21 Aug 2020 00:21:52

US3032108

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	21 Aug 2020 00:21:55

US3032108

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	21 Aug 2020 00:21:55

US3032108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	21 Aug 2020 00:22:17

US3032108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	21 Aug 2020 00:22:17

US3032108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	21 Aug 2020 00:22:17

US3032108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Samantha Wieseler (b) (4)	21 Aug 2020 00:22:17

US3032108

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	21 Aug 2020 00:22:21

US3032108

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	21 Aug 2020 00:22:21

US3032108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:33:18

US3032108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '26 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:33:18

US3032108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:33:18

US3032108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:33:18

US3032108

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:33:21

US3032108

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	28 Aug 2020 00:33:21

US3032108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'VISIT2'	System	09 Sep 2020 21:52:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User accepted default value 'Pre-Dose (PREDOSE)'	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '15:17'	Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered '9 Sep 2020 15:17'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '36.8' C	Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '88'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'bpm'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '14'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'breaths/min'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '114'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'mmHg'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '86'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'mmHg'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User accepted default value 'Post-Dose (POSTDOSE)'	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '17:10'	(b) (4)	
	Linden DeBoer (b) (4)	09 Sep 2020 22:48:35
	(b) (4)	

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered '9 Sep 2020 17:10'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '36.8' C	Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '74'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'bpm'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '14'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'breaths/min'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '87'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'mmHg'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User closed query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 03:52:40
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 03:52:35
Query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' answered with 'NCS' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Sep 2020 18:14:47
User opened query 'Per CDM : Please confirm if it is NCS/CS, If CS report as AE. Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:19:21
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'investigator determined this was normal variant for this patient' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 15:01:25
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:44:52
User entered '58'	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'mmHg'	System	09 Sep 2020 22:48:35

US3032108

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:43

US3032108

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	Linden DeBoer (b) (4)	09 Sep 2020 21:52:43

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:51

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	(b) (4)	
	Linden DeBoer (b) (4)	09 Sep 2020 21:52:51
	(b) (4)	

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Urine (URINE)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:51

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Negative (NEGATIVE)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:51

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:52:51

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4)	09 Sep 2020 21:52:51
	Linden DeBoer (b) (4)	
	(b) (4)	

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	09 Sep 2020 21:52:51
	(b) (4)	

US3032108

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered empty.	System	09 Sep 2020 21:52:51

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	09 Sep 2020 21:53:11
	(b) (4)	

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Linden DeBoer (b) (4)	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '16:38'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '9 Sep 2020 16:38'	System	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Left Arm (LEFT ARM)'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'ONCE'	System	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 21:53:11

US3032108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:53:27

US3032108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:27

US3032108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '16:06'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:27

US3032108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '9 Sep 2020 16:06'	System	09 Sep 2020 21:53:27

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '9 Sep 2020'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '16:00'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered '9 Sep 2020 16:00'	System	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Linden DeBoer (b) (4)	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered empty.	System	09 Sep 2020 21:53:40

US3032108

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	09 Sep 2020 21:53:43

US3032108

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	09 Sep 2020 21:53:43

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:13', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ae394a9c-c1e1-4d14-a4e9-43a9751f977e'	System	09 Sep 2020 22:10:30
User entered 'Yes (Y)'	System	09 Sep 2020 22:10:30

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:19', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ae394a9c-c1e1-4d14-a4e9-43a9751f977e'	System	09 Sep 2020 22:10:30
User entered '98.3'	System	09 Sep 2020 22:10:30

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:25', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ae394a9c-c1e1-4d14-a4e9-43a9751f977e'	System	09 Sep 2020 22:10:30
User entered 'No (N)'	System	09 Sep 2020 22:10:30

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:27', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'ae394a9c-c1e1-4d14-a4e9-43a9751f977e'	System	09 Sep 2020 22:10:30
User entered '09 Sep 2020 17:10'	System	09 Sep 2020 22:10:30

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 16:58'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 19:28'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 20:23'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 2'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd38e8a5e-df18-45da-9e54-94173add09d0'	System	11 Sep 2020 10:18:45
User entered 'Yes (Y)'	System	11 Sep 2020 10:18:45

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd38e8a5e-df18-45da-9e54-94173add09d0'	System	11 Sep 2020 10:18:45
User entered '97.4'	System	11 Sep 2020 10:18:45

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd38e8a5e-df18-45da-9e54-94173add09d0'	System	11 Sep 2020 10:18:45
User entered 'No (N)'	System	11 Sep 2020 10:18:45

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:41', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd38e8a5e-df18-45da-9e54-94173add09d0'	System	11 Sep 2020 10:18:45
User entered '11 Sep 2020 05:18'	System	11 Sep 2020 10:18:45

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 3'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:15:57', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7d09595b-e917-469e-b31e-58cecdb963fa'	System	11 Sep 2020 17:16:11
User entered 'Yes (Y)'	System	11 Sep 2020 17:16:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:01', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7d09595b-e917-469e-b31e-58cecdb963fa'	System	11 Sep 2020 17:16:11
User entered '97.3'	System	11 Sep 2020 17:16:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:04', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7d09595b-e917-469e-b31e-58cecdb963fa'	System	11 Sep 2020 17:16:11
User entered 'No (N)'	System	11 Sep 2020 17:16:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:08', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7d09595b-e917-469e-b31e-58cecdb963fa'	System	11 Sep 2020 17:16:11
User entered '11 Sep 2020 12:16'	System	11 Sep 2020 17:16:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 4'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:10', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f1b2fcab-faaf-4ad6-adaf-186e75ae84dc'	System	13 Sep 2020 12:35:22
User entered 'Yes (Y)'	System	13 Sep 2020 12:35:22

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:15', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f1b2fcab-faaf-4ad6-adaf-186e75ae84dc'	System	13 Sep 2020 12:35:22
User entered '97.4'	System	13 Sep 2020 12:35:22

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f1b2fcab-faaf-4ad6-adaf-186e75ae84dc'	System	13 Sep 2020 12:35:22
User entered 'No (N)'	System	13 Sep 2020 12:35:22

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:19', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f1b2fcab-faaf-4ad6-adaf-186e75ae84dc'	System	13 Sep 2020 12:35:22
User entered '13 Sep 2020 07:35'	System	13 Sep 2020 12:35:22

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 5'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:09:57', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '35ba8169-0c41-42e2-bcb4-0b18b468582f'	System	13 Sep 2020 20:10:11
User entered 'Yes (Y)'	System	13 Sep 2020 20:10:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:03', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '35ba8169-0c41-42e2-bcb4-0b18b468582f' User entered '97.4'	System	13 Sep 2020 20:10:11
	System	13 Sep 2020 20:10:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:06', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '35ba8169-0c41-42e2-bcb4-0b18b468582f'	System	13 Sep 2020 20:10:11
User entered 'No (N)'	System	13 Sep 2020 20:10:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:08', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '35ba8169-0c41-42e2-bcb4-0b18b468582f' User entered '13 Sep 2020 15:10'	System	13 Sep 2020 20:10:11
	System	13 Sep 2020 20:10:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 6'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:03:46', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '734b4ab8-d8f0-45cf-9b34-fcc5154ae265'	System	14 Sep 2020 17:05:11
User entered 'Yes (Y)'	System	14 Sep 2020 17:05:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:03:51', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '734b4ab8-d8f0-45cf-9b34-fcc5154ae265'	System	14 Sep 2020 17:05:11
User entered '97.4'	System	14 Sep 2020 17:05:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:03:53', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '734b4ab8-d8f0-45cf-9b34-fcc5154ae265'	System	14 Sep 2020 17:05:11
User entered 'No (N)'	System	14 Sep 2020 17:05:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:03:55', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '734b4ab8-d8f0-45cf-9b34-fcc5154ae265'	System	14 Sep 2020 17:05:11
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:05:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 7'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:02', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4c090b3b-867b-4978-a253-1ae26a488f8a'	System	15 Sep 2020 21:54:18
User entered 'Yes (Y)'	System	15 Sep 2020 21:54:18

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:07', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4c090b3b-867b-4978-a253-1ae26a488f8a'	System	15 Sep 2020 21:54:18
User entered '97.4'	System	15 Sep 2020 21:54:18

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:10', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4c090b3b-867b-4978-a253-1ae26a488f8a'	System	15 Sep 2020 21:54:18
User entered 'No (N)'	System	15 Sep 2020 21:54:18

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:15', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4c090b3b-867b-4978-a253-1ae26a488f8a'	System	15 Sep 2020 21:54:18
User entered '15 Sep 2020 16:54'	System	15 Sep 2020 21:54:18

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:32', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '44ad7546-1e21-4f47-ae3b-9dcec6e554d0'	System	09 Sep 2020 22:10:45
User entered 'None (1)'	System	09 Sep 2020 22:10:45

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:34', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '44ad7546-1e21-4f47-ae3b-9dcec6e554d0'	System	09 Sep 2020 22:10:45
User entered 'No (N)'	System	09 Sep 2020 22:10:45

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '44ad7546-1e21-4f47-ae3b-9dcec6e554d0'	System	09 Sep 2020 22:10:45
User entered 'No (N)'	System	09 Sep 2020 22:10:45

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '44ad7546-1e21-4f47-ae3b-9dcec6e554d0'	System	09 Sep 2020 22:10:45
User entered 'None (1)'	System	09 Sep 2020 22:10:45

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:41', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '44ad7546-1e21-4f47-ae3b-9dcec6e554d0'	System	09 Sep 2020 22:10:45
User entered '09 Sep 2020 17:10'	System	09 Sep 2020 22:10:45

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 16:58'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 19:28'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 20:23'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 2'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0dd8826c-ebf8-40e3-be39-e322b6bd49be'	System	11 Sep 2020 10:18:56
User entered 'None (1)'	System	11 Sep 2020 10:18:56

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:47', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0dd8826c-ebf8-40e3-be39-e322b6bd49be'	System	11 Sep 2020 10:18:56
User entered 'No (N)'	System	11 Sep 2020 10:18:56

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:48', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0dd8826c-ebf8-40e3-be39-e322b6bd49be'	System	11 Sep 2020 10:18:56
User entered 'No (N)'	System	11 Sep 2020 10:18:56

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:49', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0dd8826c-ebf8-40e3-be39-e322b6bd49be'	System	11 Sep 2020 10:18:56
User entered 'None (1)'	System	11 Sep 2020 10:18:56

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:51', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '0dd8826c-ebf8-40e3-be39-e322b6bd49be'	System	11 Sep 2020 10:18:56
User entered '11 Sep 2020 05:18'	System	11 Sep 2020 10:18:56

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 3'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:12', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7f1fdf95-3997-4dd6-b2ce-04111f7b5f16'	System	11 Sep 2020 17:16:26
User entered 'None (1)'	System	11 Sep 2020 17:16:26

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7f1fdf95-3997-4dd6-b2ce-04111f7b5f16'	System	11 Sep 2020 17:16:26
User entered 'No (N)'	System	11 Sep 2020 17:16:26

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7f1fdf95-3997-4dd6-b2ce-04111f7b5f16'	System	11 Sep 2020 17:16:26
User entered 'No (N)'	System	11 Sep 2020 17:16:26

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:18', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7f1fdf95-3997-4dd6-b2ce-04111f7b5f16'	System	11 Sep 2020 17:16:26
User entered 'None (1)'	System	11 Sep 2020 17:16:26

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:21', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '7f1fdf95-3997-4dd6-b2ce-04111f7b5f16'	System	11 Sep 2020 17:16:26
User entered '11 Sep 2020 12:16'	System	11 Sep 2020 17:16:26

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 4'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:23', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6c632ce6-c677-4575-aac1-01c6098ee411'	System	13 Sep 2020 12:35:32
User entered 'None (1)'	System	13 Sep 2020 12:35:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:25', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6c632ce6-c677-4575-aac1-01c6098ee411'	System	13 Sep 2020 12:35:32
User entered 'No (N)'	System	13 Sep 2020 12:35:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:26', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6c632ce6-c677-4575-aac1-01c6098ee411'	System	13 Sep 2020 12:35:32
User entered 'No (N)'	System	13 Sep 2020 12:35:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6c632ce6-c677-4575-aac1-01c6098ee411'	System	13 Sep 2020 12:35:32
User entered 'None (1)'	System	13 Sep 2020 12:35:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '6c632ce6-c677-4575-aac1-01c6098ee411'	System	13 Sep 2020 12:35:32
User entered '13 Sep 2020 07:35'	System	13 Sep 2020 12:35:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 5'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:12', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4ac77e83-54d4-4f0f-a30f-fe496e239209'	System	13 Sep 2020 20:10:22
User entered 'None (1)'	System	13 Sep 2020 20:10:22

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:14', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4ac77e83-54d4-4f0f-a30f-fe496e239209'	System	13 Sep 2020 20:10:22
User entered 'No (N)'	System	13 Sep 2020 20:10:22

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:16', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4ac77e83-54d4-4f0f-a30f-fe496e239209'	System	13 Sep 2020 20:10:22
User entered 'No (N)'	System	13 Sep 2020 20:10:22

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:18', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4ac77e83-54d4-4f0f-a30f-fe496e239209'	System	13 Sep 2020 20:10:22
User entered 'None (1)'	System	13 Sep 2020 20:10:22

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:20', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '4ac77e83-54d4-4f0f-a30f-fe496e239209'	System	13 Sep 2020 20:10:22
User entered '13 Sep 2020 15:10'	System	13 Sep 2020 20:10:22

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 6'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:03:59', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb1b61ff-6f48-4f15-bcc2-6102fa5ddf63'	System	14 Sep 2020 17:05:27
User entered 'None (1)'	System	14 Sep 2020 17:05:27

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb1b61ff-6f48-4f15-bcc2-6102fa5ddf63'	System	14 Sep 2020 17:05:27
User entered 'No (N)'	System	14 Sep 2020 17:05:27

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:15', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb1b61ff-6f48-4f15-bcc2-6102fa5ddf63'	System	14 Sep 2020 17:05:27
User entered 'No (N)'	System	14 Sep 2020 17:05:27

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:20', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb1b61ff-6f48-4f15-bcc2-6102fa5ddf63'	System	14 Sep 2020 17:05:27
User entered 'None (1)'	System	14 Sep 2020 17:05:27

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:22', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'eb1b61ff-6f48-4f15-bcc2-6102fa5ddf63'	System	14 Sep 2020 17:05:27
User entered '14 Sep 2020 12:04'	System	14 Sep 2020 17:05:27

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 7'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:19', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '3b47b98d-e13b-486b-bd1c-e4b3dce30480'	System	15 Sep 2020 21:54:32
User entered 'None (1)'	System	15 Sep 2020 21:54:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:21', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '3b47b98d-e13b-486b-bd1c-e4b3dce30480'	System	15 Sep 2020 21:54:32
User entered 'No (N)'	System	15 Sep 2020 21:54:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:23', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '3b47b98d-e13b-486b-bd1c-e4b3dce30480'	System	15 Sep 2020 21:54:32
User entered 'No (N)'	System	15 Sep 2020 21:54:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:25', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '3b47b98d-e13b-486b-bd1c-e4b3dce30480'	System	15 Sep 2020 21:54:32
User entered 'None (1)'	System	15 Sep 2020 21:54:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:27', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '3b47b98d-e13b-486b-bd1c-e4b3dce30480'	System	15 Sep 2020 21:54:32
User entered '15 Sep 2020 16:54'	System	15 Sep 2020 21:54:32

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered 'None (0)'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:46', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered 'None (0)'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:48', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered 'None (0)'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:50', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered 'None (0)'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:51', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered 'None (0)'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:53', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered 'None (0)'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:55', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered 'No (N)'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-09T17:10:58', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '21e09cf1-613f-483d-80db-ecf87682f47b'	System	09 Sep 2020 22:11:01
User entered '09 Sep 2020 17:10'	System	09 Sep 2020 22:11:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 16:58'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 19:28'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '09 Sep 2020 20:23'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 2'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:54', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered 'None (0)'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:55', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered 'None (0)'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:56', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered 'None (0)'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:58', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered 'None (0)'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:18:59', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered 'None (0)'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:19:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered 'None (0)'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:19:02', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered 'No (N)'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T05:19:05', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '140d8719-d085-490a-83d3-19ee49964aa9'	System	11 Sep 2020 10:19:09
User entered '11 Sep 2020 05:19'	System	11 Sep 2020 10:19:09

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 3'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:25', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered 'No interference with activity (1)'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered 'Some interference with activity (2)'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:34', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered 'None (0)'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:35', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered 'None (0)'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered 'None (0)'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered 'None (0)'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:42', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered 'No (N)'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-11T12:16:44', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'c4d0d89d-5aa2-47ac-8bbe-084cb1010135'	System	11 Sep 2020 17:16:51
User entered '11 Sep 2020 12:16'	System	11 Sep 2020 17:16:51

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 4'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:33', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered 'None (0)'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered 'Some interference with activity (2)'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:41', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered 'None (0)'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:42', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered 'None (0)'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered 'None (0)'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:46', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered 'None (0)'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:48', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered 'No (N)'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T07:35:50', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fa7445da-aa5a-4d3e-a332-caf290942527'	System	13 Sep 2020 12:35:55
User entered '13 Sep 2020 07:35'	System	13 Sep 2020 12:35:55

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 5'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:26', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered 'No interference with activity (1)'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered 'Some interference with activity (2)'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:36', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered 'No interference with activity (1)'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:38', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered 'None (0)'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered 'None (0)'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:41', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered 'None (0)'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:43', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered 'No (N)'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-13T15:10:47', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd1c392ef-99bf-4e48-9693-5a6195569e4c'	System	13 Sep 2020 20:10:56
User entered '13 Sep 2020 15:10'	System	13 Sep 2020 20:10:56

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 6'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:27', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered 'None (0)'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:29', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:42', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered 'None (0)'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:47', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered 'None (0)'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:50', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered 'No (N)'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-14T12:04:53', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8fe91f5c-d98e-493c-b6fe-75c28ebbfa90'	System	14 Sep 2020 17:05:46
User entered '14 Sep 2020 12:04'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	09 Sep 2020 21:53:11
User entered 'Day 7'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:33', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered 'No interference with activity (1)'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered 'Some interference with activity (2)'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered 'Some interference with activity (2)'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:43', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered 'Some interference with activity (2)'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:52', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:54', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered 'None (0)'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:56', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered 'No (N)'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-15T16:54:58', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8dd99faa-8b43-4c93-ae48-822e8e3836c1'	System	15 Sep 2020 21:55:01
User entered '15 Sep 2020 16:54'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:53:11

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Sep 2020 21:55:01
User entered 'Day 8'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:18', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'aac3c4f4-ed9-4e62-b311-db344855ac92'	System	16 Sep 2020 17:00:25
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:00:25

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:20', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'aac3c4f4-ed9-4e62-b311-db344855ac92'	System	16 Sep 2020 17:00:25
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:00:25

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Sep 2020 21:55:01
User entered 'Day 9'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	16 Sep 2020 17:00:25
User entered 'Day 10'	System	16 Sep 2020 17:00:25

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:25

US3032108

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:25

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	14 Sep 2020 17:05:46
User entered 'Day 8'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:26', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd0aa2bdf-ac18-4f7c-afd6-46272000ffed'	System	16 Sep 2020 17:00:43
User entered 'Some interference with activity (2)'	System	16 Sep 2020 17:00:43

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'd0aa2bdf-ac18-4f7c-afd6-46272000ffed'	System	16 Sep 2020 17:00:43
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:00:43

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Sep 2020 21:55:01
User entered 'Day 9'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	16 Sep 2020 17:00:43
User entered 'Day 10'	System	16 Sep 2020 17:00:43

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:43

US3032108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:43

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	14 Sep 2020 17:05:46
User entered 'Day 8'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:33', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '82d1895c-6a55-4e27-993e-bcb4b5a459be'	System	16 Sep 2020 17:00:46
User entered 'Significant; prevents daily activity (3)'	System	16 Sep 2020 17:00:46

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:35', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '82d1895c-6a55-4e27-993e-bcb4b5a459be'	System	16 Sep 2020 17:00:46
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:00:46

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Sep 2020 21:55:01
User entered 'Day 9'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	16 Sep 2020 17:00:46
User entered 'Day 10'	System	16 Sep 2020 17:00:46

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:46

US3032108

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:46

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	14 Sep 2020 17:05:46
User entered 'Day 8'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:38', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '08a995a5-5b13-4958-9a17-4c0ff5d05351'	System	16 Sep 2020 17:00:53
User entered 'Some interference with activity (2)'	System	16 Sep 2020 17:00:53

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '08a995a5-5b13-4958-9a17-4c0ff5d05351'	System	16 Sep 2020 17:00:53
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:00:53

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Sep 2020 21:55:01
User entered 'Day 9'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	16 Sep 2020 17:00:53
User entered 'Day 10'	System	16 Sep 2020 17:00:53

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:53

US3032108

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:53

US3032108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Sep 2020 21:55:01
User entered 'Day 8'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:43', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '3773eb2f-658c-4636-a0af-d9d3bff38353'	System	16 Sep 2020 17:01:04
User entered 'None (0)'	System	16 Sep 2020 17:01:04

US3032108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:45', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '3773eb2f-658c-4636-a0af-d9d3bff38353'	System	16 Sep 2020 17:01:04
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:01:04

US3032108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	14 Sep 2020 17:05:46
User entered 'Day 8'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:48', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'b5478cec-3f55-4752-b4aa-e1869a2c626d'	System	16 Sep 2020 17:01:17
User entered 'No (N)'	System	16 Sep 2020 17:01:17

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-09-16T12:00:50', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'b5478cec-3f55-4752-b4aa-e1869a2c626d'	System	16 Sep 2020 17:01:17
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:01:17

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:05:46

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	15 Sep 2020 21:55:01
User entered 'Day 9'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:55:01

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	16 Sep 2020 17:00:25
User entered 'Day 10'	System	16 Sep 2020 17:00:25

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

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)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:00:25

US3032108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:53:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:00:25

US3032108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	16 Sep 2020 23:01:41

US3032108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '16 Sep 2020'	Samantha Wieseler (b) (4)	16 Sep 2020 23:01:41

US3032108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	16 Sep 2020 23:01:41

US3032108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	Samantha Wieseler (b) (4)	16 Sep 2020 23:01:41

US3032108

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	16 Sep 2020 23:01:45

US3032108

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	16 Sep 2020 23:01:45

US3032108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	30 Sep 2020 13:00:24

US3032108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '23 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	30 Sep 2020 13:00:24

US3032108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	30 Sep 2020 13:00:24

US3032108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Sep 2020 13:00:24

US3032108

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	30 Sep 2020 13:00:27

US3032108

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	30 Sep 2020 13:00:27

US3032108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	17 Nov 2020 23:32:47

US3032108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
User entered '30 Sep 2020'	(b) (4)	
	Linden DeBoer (b) (4)	17 Nov 2020 23:32:47
	(b) (4)	

US3032108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	17 Nov 2020 23:32:47

US3032108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
User entered empty.	Linden DeBoer (b) (4)	17 Nov 2020 23:32:47

US3032108

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:11

US3032108

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	05 Oct 2020 22:30:11

US3032108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:26

US3032108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:26

US3032108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:26

US3032108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'VISIT3'	System	05 Oct 2020 22:30:26

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '14:40'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered '5 Oct 2020 14:40'	System	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '37.0' C	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '85'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'bpm'	System	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '18'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'breaths/min'	System	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '103'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'mmHg'	System	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '71'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'mmHg'	System	05 Oct 2020 22:30:49

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56

US3032108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56

US3032108

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:55

US3032108

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:30:55

US3032108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:31:03

US3032108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:31:03

US3032108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered '14:50'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:31:03

US3032108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered '5 Oct 2020 14:50'	System	05 Oct 2020 22:31:03

US3032108

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 22:31:14

US3032108

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:56
User entered 'I'	System	05 Oct 2020 22:31:14

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 64'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-09T09:49:51', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8aa557c0-4ce8-4089-9bd2-affc42b4e0ad'	System	09 Oct 2020 14:49:58
User entered 'No (N)'	System	09 Oct 2020 14:49:58

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Have you been exposed to someone with 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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-09T09:49:53', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8aa557c0-4ce8-4089-9bd2-affc42b4e0ad'	System	09 Oct 2020 14:49:58
User entered 'No (N)'	System	09 Oct 2020 14:49:58

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-09T09:49:56', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '8aa557c0-4ce8-4089-9bd2-affc42b4e0ad' User entered '09 Oct 2020 09:49:56'	System	09 Oct 2020 14:49:58
	System	09 Oct 2020 14:49:58

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '05 Oct 2020 00:01'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '09 Oct 2020 23:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 71'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-13T12:23:27', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '22956629-5d84-4673-ba7f-8490ab38204a'	System	13 Oct 2020 17:23:33
User entered 'No (N)'	System	13 Oct 2020 17:23:33

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Have you been exposed to someone with 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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-13T12:23:24', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '22956629-5d84-4673-ba7f-8490ab38204a'	System	13 Oct 2020 17:23:33
User entered 'No (N)'	System	13 Oct 2020 17:23:33

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-13T12:23:30', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '22956629-5d84-4673-ba7f-8490ab38204a'	System	13 Oct 2020 17:23:33
User entered '13 Oct 2020 12:23:30'	System	13 Oct 2020 17:23:33

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '12 Oct 2020 00:01'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '16 Oct 2020 23:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 78'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-19T04:13:23', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '800f8349-83be-4f56-af83-d5fd5a7a32fe'	System	19 Oct 2020 09:13:30
User entered 'No (N)'	System	19 Oct 2020 09:13:30

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Have you been exposed to someone with 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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-19T04:13:25', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '800f8349-83be-4f56-af83-d5fd5a7a32fe'	System	19 Oct 2020 09:13:30
User entered 'No (N)'	System	19 Oct 2020 09:13:30

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-10-19T04:13:27', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '800f8349-83be-4f56-af83-d5fd5a7a32fe'	System	19 Oct 2020 09:13:30
User entered '19 Oct 2020 04:13:27'	System	19 Oct 2020 09:13:30

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '19 Oct 2020 00:01'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '23 Oct 2020 23:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 92'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:17', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered 'Yes (Y)'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Have you been exposed to someone with 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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:20', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered 'No (N)'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
User closed query 'Per CDM CLR-Request: Response Note, Kindly Clarify the reason for As Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES recorded. Kindly confirm if any AE was experience? If yes, Kindly fill the AE page appropriately. If NO, clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 14:21:34
Query 'Per CDM CLR-Request: Response Note, Kindly Clarify the reason for As Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES recorded. Kindly confirm if any AE was experience? If yes, Kindly fill the AE page appropriately. If NO, clarify. Thanks' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4)	15 Jan 2021 01:02:52
User opened query 'Per CDM CLR-Request: Response Note, Kindly Clarify the reason for As Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES recorded. Kindly confirm if any AE was experience? If yes, Kindly fill the AE page appropriately. If NO, clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:41:53
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:41:43

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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)
Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'AE not needed' (Site from DM).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 15:06:24
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 12:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:24', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered 'Yes (Y)'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '1'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '1'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '1'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '1'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:31', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '0'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:36', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:40', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered 'Yes (Y)'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:43', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-02T12:53:46', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'f0d2d088-7891-4a1a-8b4f-0edfec5b6e69'	System	02 Nov 2020 18:53:55
User entered '02 Nov 2020 12:53:46'	System	02 Nov 2020 18:53:55

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '02 Nov 2020 00:01'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '06 Nov 2020 23:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 99'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-10T11:02:55', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '977a2642-87b2-4252-be26-e563b9a0e386'	System	10 Nov 2020 17:04:19
User entered 'No (N)'	System	10 Nov 2020 17:04:19

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Have you been exposed to someone with 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)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-10T11:02:59', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '977a2642-87b2-4252-be26-e563b9a0e386'	System	10 Nov 2020 17:04:19
User entered 'No (N)'	System	10 Nov 2020 17:04:19

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-10T11:03:02', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '977a2642-87b2-4252-be26-e563b9a0e386'	System	10 Nov 2020 17:04:19
User entered '10 Nov 2020 11:03:02'	System	10 Nov 2020 17:04:19

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '09 Nov 2020 00:01'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:21
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '13 Nov 2020 23:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32
Data entry locked.	System	06 Aug 2020 00:33:10
User entered 'Day 106'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '16 Nov 2020 00:01'	System	06 Aug 2020 00:33:10

US3032108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:02:32
Data entry locked.	System	06 Aug 2020 00:33:10
User entered '20 Nov 2020 23:59'	System	06 Aug 2020 00:33:10

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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 (e972fed65a02d584)', Time: '2020-11-24T20:29:07', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '812f1550-0595-4aaa-8fba-99d3a78d8c00'	System	25 Nov 2020 02:29:13
User entered 'No (N)'	System	25 Nov 2020 02:29:13

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Have you been exposed to someone with 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 (e972fed65a02d584)', Time: '2020-11-24T20:29:08', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '812f1550-0595-4aaa-8fba-99d3a78d8c00'	System	25 Nov 2020 02:29:13
User entered 'No (N)'	System	25 Nov 2020 02:29:13

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-11-24T20:29:11', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '812f1550-0595-4aaa-8fba-99d3a78d8c00'	System	25 Nov 2020 02:29:13
User entered '24 Nov 2020 20:29:11'	System	25 Nov 2020 02:29:13

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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 (e972fed65a02d584)', Time: '2020-12-15T10:31:24', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9a08ee3e-57e6-49e9-8d23-b5f90ad19e9e'	System	15 Dec 2020 16:31:30
User entered 'No (N)'	System	15 Dec 2020 16:31:30

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Have you been exposed to someone with 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 (e972fed65a02d584)', Time: '2020-12-15T10:31:25', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9a08ee3e-57e6-49e9-8d23-b5f90ad19e9e'	System	15 Dec 2020 16:31:30
User entered 'No (N)'	System	15 Dec 2020 16:31:30

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-12-15T10:31:28', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '9a08ee3e-57e6-49e9-8d23-b5f90ad19e9e' User entered '15 Dec 2020 10:31:28'	System	15 Dec 2020 16:31:30
	System	15 Dec 2020 16:31:30

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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 (e972fed65a02d584)', Time: '2020-12-21T10:27:35', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fcbce460-0335-450e-b18e-d5b5e4db35e8'	System	21 Dec 2020 16:27:42
User entered 'No (N)'	System	21 Dec 2020 16:27:42

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Have you been exposed to someone with 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 (e972fed65a02d584)', Time: '2020-12-21T10:27:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fcbce460-0335-450e-b18e-d5b5e4db35e8'	System	21 Dec 2020 16:27:42
User entered 'No (N)'	System	21 Dec 2020 16:27:42

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2020-12-21T10:27:39', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'fcbce460-0335-450e-b18e-d5b5e4db35e8' User entered '21 Dec 2020 10:27:39'	System	21 Dec 2020 16:27:42
	System	21 Dec 2020 16:27:42

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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 (e972fed65a02d584)', Time: '2021-01-04T13:02:21', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '56aacb78-b135-4449-9c0d-741016e313ca'	System	04 Jan 2021 19:02:46
User entered 'No (N)'	System	04 Jan 2021 19:02:46

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Have you been exposed to someone with 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 (e972fed65a02d584)', Time: '2021-01-04T13:02:29', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '56aacb78-b135-4449-9c0d-741016e313ca'	System	04 Jan 2021 19:02:46
User entered 'Yes (Y)'	System	04 Jan 2021 19:02:46

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Please 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 (e972fed65a02d584)', Time: '2021-01-04T13:02:34', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '56aacb78-b135-4449-9c0d-741016e313ca'	System	04 Jan 2021 19:02:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 19:02:46

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e972fed65a02d584)', Time: '2021-01-04T13:02:37', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '56aacb78-b135-4449-9c0d-741016e313ca' User entered '04 Jan 2021 13:02:37'	System	04 Jan 2021 19:02:46

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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 (9b7e0e747c59814a)', Time: '2021-03-01T10:35:08-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '41e8571b-3ea4-4814-a8e4-020411f38fad'	System	01 Mar 2021 16:35:20
User entered 'No (N)'	System	01 Mar 2021 16:35:20

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Have you been exposed to someone with 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 (9b7e0e747c59814a)', Time: '2021-03-01T10:35:13-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '41e8571b-3ea4-4814-a8e4-020411f38fad'	System	01 Mar 2021 16:35:20
User entered 'No (N)'	System	01 Mar 2021 16:35:20

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7e0e747c59814a)', Time: '2021-03-01T10:35:17-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '41e8571b-3ea4-4814-a8e4-020411f38fad' User entered '01 Mar 2021 10:35:17'	System	01 Mar 2021 16:35:20
	System	01 Mar 2021 16:35:20

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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 (9b7e0e747c59814a)', Time: '2021-03-12T09:23:34-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '88c41991-f62c-45b4-9b01-600acc823634'	System	12 Mar 2021 15:23:47
User entered 'No (N)'	System	12 Mar 2021 15:23:47

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Have you been exposed to someone with 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 (9b7e0e747c59814a)', Time: '2021-03-12T09:23:37-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '88c41991-f62c-45b4-9b01-600acc823634'	System	12 Mar 2021 15:23:47
User entered 'No (N)'	System	12 Mar 2021 15:23:47

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7e0e747c59814a)', Time: '2021-03-12T09:23:43-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '88c41991-f62c-45b4-9b01-600acc823634'	System	12 Mar 2021 15:23:47
User entered '12 Mar 2021 09:23:43'	System	12 Mar 2021 15:23:47

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[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 (9b7e0e747c59814a)', Time: '2021-04-02T09:11:04-05:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '60ea0e3d-a648-4a67-93f1-aab1236655e7'	System	02 Apr 2021 14:11:13
User entered 'No (N)'	System	02 Apr 2021 14:11:13

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

Have you been exposed to someone with 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 (9b7e0e747c59814a)', Time: '2021-04-02T09:11:07-05:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '60ea0e3d-a648-4a67-93f1-aab1236655e7'	System	02 Apr 2021 14:11:13
User entered 'No (N)'	System	02 Apr 2021 14:11:13

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7e0e747c59814a)', Time: '2021-04-02T09:11:09-05:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: '60ea0e3d-a648-4a67-93f1-aab1236655e7'	System	02 Apr 2021 14:11:13
User entered '02 Apr 2021 09:11:09'	System	02 Apr 2021 14:11:13

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 14:02:32

US3032108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:32
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 14:02:32

US3032108

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:18

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 22:09:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7e0e747c59814a)', Time: '2021-03-01T10:34:59-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'b4eb3731-ff6b-4c57-aa7e-a53df3ad3f8b'	System	01 Mar 2021 16:35:07
User entered 'No (N)'	System	01 Mar 2021 16:35:07

US3032108

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:09:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7e0e747c59814a)', Time: '2021-03-01T10:35:02-06:00', User OID: 'PatientReportedOutcome (US3032108)', ODM File OID: 'b4eb3731-ff6b-4c57-aa7e-a53df3ad3f8b' User entered '01 Mar 2021 10:35:02'	System	01 Mar 2021 16:35:07
	System	01 Mar 2021 16:35:07

US3032108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:34:45
User entered 'Yes (Y)'	Russell Herstein (b) (4)	07 Nov 2020 00:15:49

US3032108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:34:45
User entered '03 Nov 2020'	Russell Herstein (b) (4)	07 Nov 2020 00:15:49

US3032108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:34:45
User entered 'Contact Made (CONTACT MADE)'	Russell Herstein (b) (4)	07 Nov 2020 00:15:49

US3032108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:34:45
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	07 Nov 2020 00:15:49

US3032108

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:34:45
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	07 Nov 2020 00:15:52

US3032108

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:44
User entered 'I'	System	07 Nov 2020 00:15:52

US3032108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:01
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Dec 2020 23:23:19

US3032108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:01
User entered '7 Dec 2020'	(b) (4) Linden DeBoer (b) (4)	14 Dec 2020 23:23:19

US3032108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	14 Dec 2020 23:23:19

US3032108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:01
User entered empty.	Linden DeBoer (b) (4)	14 Dec 2020 23:23:19

US3032108

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:09
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:01
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Dec 2020 23:23:23

US3032108

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:09
User entered 'I'	System	14 Dec 2020 23:23:23

US3032108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:19
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	27 Jan 2021 18:43:00

US3032108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:19
User entered '04 Jan 2021'	Samantha Wieseler (b) (4)	27 Jan 2021 18:43:00

US3032108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:19
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	27 Jan 2021 18:43:00

US3032108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:19
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	27 Jan 2021 18:43:00

US3032108

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:19
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	27 Jan 2021 18:43:03

US3032108

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered 'I'	System	27 Jan 2021 18:43:03

US3032108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	08 Mar 2021 15:23:16

US3032108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered '03 Feb 2021'	Samantha Wieseler (b) (4)	08 Mar 2021 15:23:16

US3032108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 15:23:16

US3032108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered empty.	Samantha Wieseler (b) (4)	08 Mar 2021 15:23:16

US3032108

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	08 Mar 2021 15:23:20

US3032108

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered 'I'	System	08 Mar 2021 15:23:20

US3032108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	09 Mar 2021 01:09:40

US3032108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered '8 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Mar 2021 01:09:40

US3032108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	09 Mar 2021 01:09:40

US3032108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered 'VISIT4'	System	09 Mar 2021 01:09:40

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered empty.	System	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered empty.	System	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered empty.	System	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered empty.	System	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered empty.	System	29 Mar 2021 21:07:58

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11

US3032108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11

US3032108

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Mar 2021 01:09:50

US3032108

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered empty.	Kelsey Kelley (b) (4)	09 Mar 2021 01:09:50

US3032108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Mar 2021 01:10:12

US3032108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered '8 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Mar 2021 01:10:12

US3032108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered '14:52'	Kelsey Kelley (b) (4)	09 Mar 2021 01:10:12

US3032108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered '8 Mar 2021 14:52'	System	09 Mar 2021 01:10:12

US3032108

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:01
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Mar 2021 01:09:19

US3032108

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:11
User entered 'I'	System	09 Mar 2021 01:09:19

US3032108

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	05 Apr 2021 14:51:50

US3032108

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '5 Apr 2021'	(b) (4) Chelsie Nutsch (b) (4)	05 Apr 2021 14:51:50

US3032108

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	05 Apr 2021 14:51:50

US3032108

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	05 Apr 2021 14:51:50

US3032108

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	05 Apr 2021 14:51:53

US3032108

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:11
User entered 'I'	System	05 Apr 2021 14:51:53

US3032108

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:49:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	03 Mar 2021 16:21:41

US3032108

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:49:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:41

US3032108

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:49:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:41

US3032108

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'UNBLND_DECIDE'	System	03 Mar 2021 16:21:41

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:59

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:46
User entered '0'	(b) (4)	
	Linden DeBoer (b) (4)	10 Mar 2021 20:31:34
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:38:07

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:59

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:46
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Linden DeBoer (b) (4)	10 Mar 2021 20:31:34
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:38:07

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:59

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:59

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:59

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:21:59

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4)	
	Kelsey Kelley (b) (4)	03 Mar 2021 16:21:59
	(b) (4)	

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '1'	System	03 Mar 2021 16:21:59

US3032108

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'I'	System	03 Mar 2021 16:21:59

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	03 Mar 2021 16:24:30
DataPoint set to visible.	System	03 Mar 2021 16:21:59

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	03 Mar 2021 16:24:30
DataPoint set to visible.	System	03 Mar 2021 16:21:59

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '18:10'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '2 Mar 2021 18:10'	System	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '72'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'bpm'	System	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'breaths/min'	System	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '95'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'mmHg'	System	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '70'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'mmHg'	System	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:30

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	03 Mar 2021 16:24:30
DataPoint set to visible.	System	03 Mar 2021 16:21:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '19:01'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered '2 Mar 2021 19:01'	System	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '76'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'bpm'	System	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'breaths/min'	System	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '94'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'mmHg'	System	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:50:58
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '68'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered 'mmHg'	System	03 Mar 2021 16:24:47

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:51:06
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:02

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:51:06
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:24:02

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:52:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Date of test \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:52:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:52:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Urine (URINE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:52:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:52:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:52:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
DataPoint Verified.		31 Mar 2021 20:52:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:15
User entered empty.	System	03 Mar 2021 16:22:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
User entered 'mRNA-1273'	System	03 Mar 2021 16:23:26
DataPoint set to visible.	System	03 Mar 2021 16:21:59

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	Kelsey Kelley (b) (4)	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '18:29'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
User entered '2 Mar 2021 18:29'	System	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:15
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:15
User entered 'ONCE'	System	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 16:23:26

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:09

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:09

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '17:53'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:09

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
User entered '2 Mar 2021 17:53'	System	03 Mar 2021 16:22:09

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:40
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4)	
	Kelsey Kelley (b) (4)	03 Mar 2021 16:22:33
	(b) (4)	

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:40
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).		16 Mar 2021 07:40:00
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'sample is marked in preclarus as at the lab' (Site from DM).	Samantha Wieseler (b) (4)	15 Mar 2021 16:25:01
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:39:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '2 Mar 2021'	Kelsey Kelley (b) (4)	03 Mar 2021 16:22:33

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:18

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:52:40
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered '18:00'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:33

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:18

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
User entered '2 Mar 2021 18:00'	System	03 Mar 2021 16:22:33

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
DataPoint Verified.		31 Mar 2021 20:53:05
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:01:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 16:22:36

US3032108

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:15:10
User entered 'I'	System	03 Mar 2021 16:22:36

US3032108

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:40
DataPoint Verified.		31 Mar 2021 20:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:46
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	10 Mar 2021 20:32:36
	(b) (4)	

US3032108

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:40
DataPoint Verified.		31 Mar 2021 20:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:46
User entered '9 Mar 2021'	(b) (4) Linden DeBoer (b) (4) (b) (4)	10 Mar 2021 20:32:36

US3032108

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:40
DataPoint Verified.		31 Mar 2021 20:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	10 Mar 2021 20:32:36

US3032108

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:40
DataPoint Verified.		31 Mar 2021 20:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:46
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	10 Mar 2021 20:32:36

US3032108

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:40
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:46
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Mar 2021 20:32:41

US3032108

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:40
User entered 'I'	System	10 Mar 2021 20:32:41

US3032108

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:40
User entered '1'	System	10 Mar 2021 20:32:41
DataPoint set to visible.	System	10 Mar 2021 20:32:41

US3032108

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:40:56

US3032108

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '5 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:40:56

US3032108

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:40:56

US3032108

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	05 Apr 2021 18:40:56

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '5 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '11:40'	Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 11:40'	System	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '37.1' C	Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '16'	Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '124'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 18:42:19

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '5 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '12:43'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 12:43'	System	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '37.0' C	Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '71'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '18'	Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '101'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '82'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 18:43:10

US3032108

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:42:29

US3032108

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '5 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:42:29

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '5 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Negative (NEGATIVE)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'No (N)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:53:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:41:08

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	05 Apr 2021 18:41:36
DataPoint set to visible.	System	10 Mar 2021 20:32:41

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '5 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered '12:12'	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 12:12'	System	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:18

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Apr 2021 18:41:36

US3032108

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:32:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 18:41:49

US3032108

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 18:41:49

US3032108

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:10:40

US3032108

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:19
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:10:40

US3032108

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:10:40

US3032108

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:19
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:10:40

US3032108

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:10:46

US3032108

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 20:10:46

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:53:18

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:02:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:39:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	17 Nov 2020 23:34:58
	(b) (4)	
User entered '19 Aug 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	17 Nov 2020 23:34:58
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered '18 Aug 2020'	Kelsey Kelley (b) (4)	28 Aug 2020 00:24:13
	(b) (4)	

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:53:18

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:02:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:39:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'l'	Kelsey Kelley (b) (4)	28 Aug 2020 00:24:13

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:53:18

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:02:26
DataPoint Verified.		31 Mar 2021 20:39:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:24:13

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:53:18

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:02:26
DataPoint Verified.		31 Mar 2021 20:39:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:24:13

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:53:18

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:02:26
DataPoint Verified.		31 Mar 2021 20:39:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:24:13

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	17 Nov 2020 23:35:06
	(b) (4)	
User entered '19 Aug 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	17 Nov 2020 23:35:06
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
Query 'Per ETRTR: Please confirm rationale for performing this visit. If related to Adverse Event, ensure complete reporting, thanks,' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:40:19
User opened query 'Per ETRTR: Please confirm rationale for performing this visit. If related to Adverse Event, ensure complete reporting, thanks,' (Site from CRA).		01 Sep 2020 23:23:46
User entered '18 Aug 2020'	Kelsey Kelley (b) (4)	28 Aug 2020 00:25:20
	(b) (4)	

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:40:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '09:17'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
User entered '19 Aug 2020 09:17'	System	17 Nov 2020 23:35:06
User entered '18 Aug 2020 09:17'	System	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '98.3' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '90'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
User entered 'bpm'	System	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
User entered 'breaths/min'	System	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:41:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '107'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
User entered 'mmHg'	System	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
DataPoint Verified.		31 Mar 2021 20:42:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37
User entered 'mmHg'	System	28 Aug 2020 00:25:20

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:37

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:44
DataPoint Verified.		31 Mar 2021 20:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:25:25

US3032108

Folder: Unscheduled 19 Aug 2020

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:03:44
DataPoint Verified.		31 Mar 2021 20:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	17 Nov 2020 23:35:15
Signature has been broken.	Linden DeBoer (b) (4)	17 Nov 2020 23:35:15
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	17 Nov 2020 23:35:15
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	17 Nov 2020 23:34:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
User entered '18 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:25:25

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:53:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:45
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and HEADACHE (start date: Day 3; end date: Day 8) and JOINT ACHES (start date: Day 6; end date: Day 8) persist beyond Day 7 . 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).		09 Apr 2021 12:04:24
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES (start date: Day 5; end date: Day 9) persist beyond Day 7. 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)	09 Apr 2021 12:04:22
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and HEADACHE (start date: Day 3; end date: Day 8) and JOINT ACHES (start date: Day 6; end date: Day 8) persist beyond Day 7 . 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 'Updated AE Log' (Site from DM).	Kelsey Kelley (b) (4)	06 Apr 2021 22:31:19
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES (start date: Day 5; end date: Day 9) persist beyond Day 7. 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 'Updated AE log' (Site from DM).	Kelsey Kelley (b) (4)	06 Apr 2021 22:30:16

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:53:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and HEADACHE (start date: Day 3; end date: Day 8) and JOINT ACHES (start date: Day 6; end date: Day 8) persist beyond Day 7 . 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)	05 Apr 2021 14:43:23
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES (start date: Day 5; end date: Day 9) persist beyond Day 7. 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.	(b) (4), (b) (6)	05 Apr 2021 14:43:19
' (Site from DM).		
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 5 - 13SEP2020; end date: Day 8 - 16SEP2020). 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.'	(b) (4), (b) (6)	02 Apr 2021 20:49:57
(Site from DM).		
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 4 - 08AUG2020 ; end date: Day 8 - 12AUG2020). 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.'	(b) (4), (b) (6)	02 Apr 2021 20:49:48
(Site from DM).		
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 5 - 13SEP2020; end date: Day 8 - 16SEP2020). 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.'	Samantha Wieseler	(b) (4) 31 Mar 2021 12:59:25
answered with 'no AE needed' (Site from DM).	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events Summary

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[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 4 - 08AUG2020 ; end date: Day 8 - 12AUG2020). 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 'no AE needed' (Site from DM).	Samantha Wieseler (b) (4)	31 Mar 2021 12:59:10
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 5 - 13SEP2020; end date: Day 8 - 16SEP2020). 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)	31 Mar 2021 02:54:06
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 4 - 08AUG2020 ; end date: Day 8 - 12AUG2020). 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)	31 Mar 2021 02:53:59
User closed query 'Per CDM, DM CLR re-query on Safety Follow Up Diary, Day 91: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes. There was a response "will update accordingly"; however, there is no corresponding AE for this recorded data. Please update to record the AE as applicable, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:20:30

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Folder: Adverse Events

Form: Adverse Events Summary

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[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per CDM, DM CLR re-query on Safety Follow Up Diary, Day 91: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes. There was a response "will update accordingly"; however, there is no corresponding AE for this recorded data. Please update to record the AE as applicable, else clarify. ' answered with 'No AE needed' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Feb 2021 23:37:56
User opened query 'Per CDM, DM CLR re-query on Safety Follow Up Diary, Day 91: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes. There was a response "will update accordingly"; however, there is no corresponding AE for this recorded data. Please update to record the AE as applicable, else clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 14:21:21
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:55:46
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	21 Aug 2020 00:22:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, if this pertains to the same HEADACHE (AE #1) then this is a duplicate entry. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification that these are 2 different type of HEADACHE.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 01:46:22
Query 'Per DM CLR - RQ: Site's response noted. However, if this pertains to the same HEADACHE (AE #1) then this is a duplicate entry. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification that these are 2 different type of HEADACHE.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	15 Feb 2021 17:57:19
User opened query 'Per DM CLR - RQ: Site's response noted. However, if this pertains to the same HEADACHE (AE #1) then this is a duplicate entry. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification that these are 2 different type of HEADACHE.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:45:54
User closed query 'Per DM CLR-RQ: Site's response noted. However, even if this AE was a medically attended AE, they are still the same AE of headache. Please reconcile dates of both entries and update so there is no overlap or delete duplicate record as applicable. Otherwise, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:16:21
Query 'Per DM CLR-RQ: Site's response noted. However, even if this AE was a medically attended AE, they are still the same AE of headache. Please reconcile dates of both entries and update so there is no overlap or delete duplicate record as applicable. Otherwise, provide further clarification.' answered with 'SUBJECT REPORTED HEADACHE WAS DIFFERENT AND MORE INTENSE THAN USUAL. ' (Site from DM).	Russell Herstein (b) (4)	20 Nov 2020 22:54:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Site's response noted. However, even if this AE was a medically attended AE, they are still the same AE of headache. Please reconcile dates of both entries and update so there is no overlap or delete duplicate record as applicable. Otherwise, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:29:13
Query 'Per DM CLR: Please review the dates of this AE as it was note to be within the dates of the recorded AE #1 (HEADACHE). Please reconcile dates of both events and update so there is no overlap. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:27:28
User opened query 'Per DM CLR: Please review the dates of this AE as it was note to be within the dates of the recorded AE #1 (HEADACHE). Please reconcile dates of both events and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:17:47
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC HEADACHE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:53:19
User closed query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:53:15
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC HEADACHE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'TERM CORRECT PER SOURCE AE LOG' (Site from DM).	Russell Herstein (b) (4)	30 Sep 2020 14:52:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' answered with 'This differs due to it being MAAE and not solicited' (Site from DM).	Kelsey Kelley (b) (4)	30 Sep 2020 12:57:14
User opened query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:35:52
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC HEADACHE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:35:43
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headache - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:52:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:52:34
Data point term sent to Coder	System	28 Aug 2020 00:29:29
User entered 'tension headache'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'No (N)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:50:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 22:50:11
User entered 'No (N)' reason for change: Data Entry Error	Christy Lee (b) (4)	14 Sep 2020 22:50:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 00:28:32
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:44:51
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 14:08:47
User closed query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 14:08:47
User entered '08 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Sep 2020 14:08:47
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 14:08:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Sep 2020 14:08:19
User entered '25 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Sep 2020 14:08:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Aug 2020 00:28:32
User entered ' Aug 2020' (non-conformant).	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Sep 2020 14:08:19
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '25 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Sep 2020 14:08:19
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:56:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 22:56:18
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Christy Lee (b) (4)	14 Sep 2020 22:56:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 00:28:32
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:56:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 22:56:18
User entered 'No (N)' reason for change: Data Entry Error	Christy Lee (b) (4)	14 Sep 2020 22:56:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 00:28:32
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:49:57
User closed query 'Per CDM: Please note that per page 37 of CCGs v2.0, an Adverse event should be recorded as 'Not applicable' only if it has started before the first dose. In all other cases 'Related' or 'Not related' should be selected for a Relationship to investigational product and Relationship to Study Procedure. Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 04:13:33
Query 'Per CDM: Please note that per page 37 of CCGs v2.0, an Adverse event should be recorded as 'Not applicable' only if it has started before the first dose. In all other cases 'Related' or 'Not related' should be selected for a Relationship to investigational product and Relationship to Study Procedure. Please update as appropriate. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Nov 2020 20:36:06
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Nov 2020 20:36:00
User entered 'Related (RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Nov 2020 20:36:00
User opened query 'Per CDM: Please note that per page 37 of CCGs v2.0, an Adverse event should be recorded as 'Not applicable' only if it has started before the first dose. In all other cases 'Related' or 'Not related' should be selected for a Relationship to investigational product and Relationship to Study Procedure. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:27:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:02
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:56:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 22:56:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Christy Lee (b) (4) (b) (4)	14 Sep 2020 22:56:18
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 00:28:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:28:32

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:22
User closed query 'Per CDM: AE started after first dose, yet Not Applicable is selected for Relationship to Study Procedure. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:17:57
Query 'Per CDM: AE started after first dose, yet Not Applicable is selected for Relationship to Study Procedure. Please review and update as appropriate.' answered with 'not related is marked' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	23 Nov 2020 18:54:26
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:14:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:14:38
User opened query 'Per CDM: AE started after first dose, yet Not Applicable is selected for Relationship to Study Procedure. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:32:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:02
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:56:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 22:56:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Christy Lee (b) (4) (b) (4)	14 Sep 2020 22:56:18
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 00:28:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'None (NONE)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:10
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	15 Feb 2021 17:57:29
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '1'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Sep 2020 14:08:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 22:56:18

US3032108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 00:28:32

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:23:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:23:26
Data point term sent to Coder	System	06 Apr 2021 22:22:38
User entered 'arthralgia'	Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '9 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User entered empty.	System	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '13 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User entered empty.	System	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'None (NONE)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[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 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User entered '0'	System	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04
User entered '0'	System	06 Apr 2021 22:21:40

US3032108

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:04

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:23:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:23:26
Data point term sent to Coder	System	06 Apr 2021 22:22:38
User entered 'myalgia'	Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '9 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User entered empty.	System	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '12 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User entered empty.	System	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'None (NONE)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[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 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User entered '0'	System	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11
User entered '0'	System	06 Apr 2021 22:22:20

US3032108

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:24:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:24:26
Data point term sent to Coder	System	06 Apr 2021 22:23:39
User entered 'arthralgia'	Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '14 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User entered empty.	System	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '16 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User entered empty.	System	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[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 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User entered '0'	System	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17
User entered '0'	System	06 Apr 2021 22:23:05

US3032108

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:17

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:25:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:25:27
Data point term sent to Coder	System	06 Apr 2021 22:24:40
User entered 'myalgia'	Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '13 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User entered empty.	System	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '16 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User entered empty.	System	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[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 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User entered '0'	System	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29
User entered '0'	System	06 Apr 2021 22:23:50

US3032108

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:29

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:25:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:25:27
Data point term sent to Coder	System	06 Apr 2021 22:24:40
User entered 'fatigue'	Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '11 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User entered empty.	System	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '16 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User entered empty.	System	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[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 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User entered '0'	System	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34
User entered '0'	System	06 Apr 2021 22:24:30

US3032108

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:34

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:26:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 22:26:29
Data point term sent to Coder	System	06 Apr 2021 22:25:40
User entered 'headache'	Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '11 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User entered empty.	System	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

Form: Adverse Events (8)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '16 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User entered empty.	System	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:53:18

[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 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:05:56
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User entered '0'	System	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40
User entered '0'	System	06 Apr 2021 22:25:09

US3032108

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:06:40

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:31
User entered 'USA-US032-2021-mRNA-1273-P301000012'	System	03 May 2021 12:57:23
User entered 'New'	(b) (4), (b) (6)	03 May 2021 12:57:23

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Tooth decay - version MedDRA\\23.0.	Coder Import (b) (4)	01 May 2021 17:01:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 May 2021 17:01:06
Data point term sent to Coder	System	30 Apr 2021 18:44:52
User entered 'Tooth Decay on Right side of the mouth.'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'No (N)'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered '12 Apr 2021'	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:31
User entered empty.	Linden DeBoer (b) (4) (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered 'No (N)'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	30 Apr 2021 18:44:26
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Apr 2021 18:44:26
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Apr 2021 18:44:00
User entered '25 Apr 2021'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered '0'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered '0'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered 'I'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered '22 Apr 2021'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered '25 Apr 2021'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered 'No (N)'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered empty.	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered '0'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered '0'	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered '0'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered '0'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered '1'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered 'I'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	30 Apr 2021 18:44:26
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered empty.	(b) (4) Linden DeBoer (b) (4)	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered 'Subject went to dentist for a rotten tooth on the right side of the mouth. The tooth was pulled at that time. Then subject developed severe pain and swelling. Subject went to the ER. The ER then sent subject home and told her to go to the dentist. When at the dentist the dentist then said to go to ER. At that time the ER did a CT Scan and realized that the infection was severe and required treatment that meet inpatient criteria. They did a balloon sinuplasty to help with the infection and drainage. Subject was discharged in stable condition on 25 Apr 2021. Subject has signed a medical release form at this time. Will update SAE as more information becomes available.'	(b) (4)	
	Linden DeBoer (b) (4)	30 Apr 2021 18:44:00
	(b) (4)	

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 18:44:00

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Adverse event](#)

Audit	User		Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute maxillary sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	03 May 2021 16:29:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	03 May 2021 16:29:28
Data point term sent to Coder	System		03 May 2021 16:25:56
User entered 'acute right maxillary sinusitis'	Kelsey Kelley (b) (4)	(b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[None](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 16:25:50

US3032108

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:53:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 16:25:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:53:18

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:45
User closed query 'Per CDM : Please note the Con med has not been updated. Kindly update for Dose 1 Day 4, 5 , 7 ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:52:28
Query 'Per CDM : Please note the Con med has not been updated. Kindly update for Dose 1 Day 4, 5 , 7 ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:02:27
User opened query 'Per CDM : Please note the Con med has not been updated. Kindly update for Dose 1 Day 4, 5 , 7 ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:20:01
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:55:46
User closed query 'Per DM CLR: Per Diary Dose 1 Day 4-5 & 7, 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 clarify.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:41:19
Query 'Per DM CLR: Per Diary Dose 1 Day 4-5 & 7, 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 clarify.' answered with 'Con meds have been updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	16 Sep 2020 14:18:58
User opened query 'Per DM CLR: Per Diary Dose 1 Day 4-5 & 7, 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 clarify.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:44:11
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:08:38

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:08:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:08:23
Data point term sent to Coder	System	21 Oct 2020 16:02:24
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	21 Oct 2020 16:01:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 07:19:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 07:19:03
Data point term sent to Coder	System	06 Aug 2020 01:10:32
User entered 'albuterol'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:46:58
	(b) (4)	
User closed query 'Per DM CLR: Please record the medical condition of asthma only.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:47:13
Query 'Per DM CLR: Please record the medical condition of asthma only.' answered with 'done' (Site from DM).	Kelsey Kelley (b) (4)	21 Oct 2020 16:02:19
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	21 Oct 2020 16:01:49
	(b) (4)	
User entered 'ASTHMA' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	21 Oct 2020 16:01:49
	(b) (4)	
User opened query 'Per DM CLR: Please record the medical condition of asthma only.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
	(b) (4)	
User entered 'medical history: asthma'	Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48
	(b) (4)	

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 07:16:29
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	16 Sep 2020 23:34:55
User entered '90' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	16 Sep 2020 23:34:34
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 09:12:48
User entered '2'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Dose unit](#)

Audit	User		Time (GMT)
User signature succeeded.	Keith Vrbicky	(b) (4)	01 Oct 2020 21:50:02
	(b) (4)		
User entered 'ug (ug)' reason for change: Data Entry Error	Kelsey Kelley	(b) (4)	16 Sep 2020 23:34:34
	(b) (4)		
User entered 'puff (PUFF)'	Kelsey Kelley	(b) (4)	06 Aug 2020 01:09:48
	(b) (4)		

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:40:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 01:09:48
User entered 'un UNK 2005'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 01:09:48

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 23:04:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 23:04:40
Data point term sent to Coder	System	29 Sep 2020 21:03:15
Coding entries removed.	Samantha Wieseler (b) (4)	29 Sep 2020 21:02:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 10:05:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 10:05:50
Data point term sent to Coder	System	16 Sep 2020 23:34:46
Coding entries removed.	Kelsey Kelley (b) (4)	16 Sep 2020 23:34:04
User entered 'EXCEDRIN MIGRAINE (ACETAMINOPHEN, ASPIRIN, CAFFEINE)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Sep 2020 23:34:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 00:52:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 00:52:35
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Aug 2020 00:30:29
User entered 'Excedrin migraine'	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53
	(b) (4)	

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'No (N)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'HEADACHE' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	29 Sep 2020 21:02:53
User entered 'adverse event: headache'	(b) (4)	
	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53
	(b) (4)	

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:46:58
User closed query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash (e.g. 5/325). If so please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 09:46:48
Query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash (e.g. 5/325). If so please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:58:42
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:58:38
User entered '250/250/65' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:58:38
User opened query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash (e.g. 5/325). If so please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:27:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:02
User closed query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 07:16:43
Query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. " ' answered with 'DATA UPDATED' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	16 Sep 2020 23:34:12
User entered '250,250,65' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	16 Sep 2020 23:34:04
User opened query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:47:49

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1-2'	Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Sep 2020 23:34:04
User entered 'tablet (TABLET)'	(b) (4)	
	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53
	(b) (4)	

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53
	(b) (4)	

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:10:55
Signature has been broken.	Linden DeBoer (b) (4)	17 Nov 2020 23:17:41
User entered '08 Aug 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	17 Nov 2020 23:17:41
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '05 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	29 Sep 2020 21:03:01
User entered '08 Aug 2020'	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:10
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 01:48:36
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:08
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:03
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:03
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:46:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:02
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:10
Signature has been broken.	Samantha Wieseler (b) (4)	15 Feb 2021 17:58:03
User entered '25 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	15 Feb 2021 17:58:03
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User entered empty.	System	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User entered empty.	System	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:17:01
User entered empty.	System	28 Aug 2020 00:29:53

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE, PRODUCTSYNONYM: FIORINAL [ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:24:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:24:21
Data point term sent to Coder	System	21 Oct 2020 16:03:25
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	21 Oct 2020 16:02:30
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE, PRODUCTSYNONYM: FIORINAL [ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:48:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:48:56
Data point term sent to Coder	System	16 Sep 2020 23:33:45
Data point term sent to Coder	System	16 Sep 2020 14:18:11
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	16 Sep 2020 14:17:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'Ingredients have been added' (Site from System).	Kelsey Kelley (b) (4)	16 Sep 2020 14:17:50
Data point term sent to Coder	System	14 Sep 2020 23:05:23
User entered 'Fiorinal (aspirin, butalbital, caffeine)' reason for change: Data Entry Error	Christy Lee (b) (4)	14 Sep 2020 23:04:42
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	04 Sep 2020 11:24:38
Data point term sent to Coder	System	28 Aug 2020 00:33:32
User entered 'fiorinal'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:46:58
User closed query '	(b) (4)	
Per DM CLR: Please record the medical condition of Headache only' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:47:06
Query '	Kelsey Kelley (b) (4)	21 Oct 2020 16:02:38
Per DM CLR: Please record the medical condition of Headache only' answered with 'done' (Site from DM).	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	21 Oct 2020 16:02:30
	(b) (4)	
User entered 'HEADACHE' reason for change: New Information	Kelsey Kelley (b) (4)	21 Oct 2020 16:02:30
	(b) (4)	
User opened query '	(b) (4), (b) (6)	21 Oct 2020 15:11:47
Per DM CLR: Please record the medical condition of Headache only' (Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
	(b) (4)	
User entered 'ADVERSE EVENT: HEADACHE' reason for change: New Information	Kelsey Kelley (b) (4)	16 Sep 2020 23:33:08
	(b) (4)	
User entered 'headache'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35
	(b) (4)	

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User closed query 'Per DM CLR: Please review recorded dosage as it include the units of each dose. Please update to remove the units from the dose field as it is already reflected or recorded on the unit field. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:52:10
Query 'Per DM CLR: Please review recorded dosage as it include the units of each dose. Please update to remove the units from the dose field as it is already reflected or recorded on the unit field. Please update as appropriate or provide clarification.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:02:05
User entered '325/50/40' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:01:58
User opened query 'Per DM CLR: Please review recorded dosage as it include the units of each dose. Please update to remove the units from the dose field as it is already reflected or recorded on the unit field. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:24:36
User closed query 'Per DM CLR: Please review if this is a combination drug; Note, only one component has been recorded in the dose field. Reconcile and update per CRF guidelines.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 07:17:06
Query 'Per DM CLR: Please review if this is a combination drug; Note, only one component has been recorded in the dose field. Reconcile and update per CRF guidelines.' answered with 'The other component amounts have been added' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	16 Sep 2020 14:17:29
User entered '325mg,50mg, 40mg' reason for change: Data Entry Error	Christy Lee (b) (4) (b) (4)	14 Sep 2020 23:05:16
User entered '50mg' reason for change: Data Entry Error	Christy Lee (b) (4) (b) (4)	14 Sep 2020 23:04:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a combination drug; Note, only one component has been recorded in the dose field. Reconcile and update per CRF guidelines. ' (Site from DM). User entered '40'	(b) (4), (b) (6)	12 Sep 2020 03:49:25
	Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'other (OTHER)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'every 4 hours as needed'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '24 Aug 2020'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered '0'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:10
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 01:51:52
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:28
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:23
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:23
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:46:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:02
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:10
Signature has been broken.	Samantha Wieseler (b) (4)	15 Feb 2021 17:58:23
User entered '25 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	15 Feb 2021 17:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered empty.	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:02
User entered 'No (N)'	Kelsey Kelley (b) (4)	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User entered empty.	System	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User entered empty.	System	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:12
User entered empty.	System	28 Aug 2020 00:32:35

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 16:27:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 16:27:25
Data point term sent to Coder	System	03 May 2021 16:26:57
User entered 'Hydrocodone/acetaminophen'	Kelsey Kelley (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'acute right maxillary sinusitis'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '3/325'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 16:26:51

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 16:29:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 16:29:29
Data point term sent to Coder	System	03 May 2021 16:27:57
User entered 'clindamycin'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'acute right maxillary sinusitis'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 16:27:50

US3032108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 16:27:50

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:53:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Signature has been broken.	Kelsey Kelley (b) (4)	03 May 2021 16:28:21
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	03 May 2021 16:28:21
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:55:46
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:09:55
	(b) (4)	

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Apr 2021'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:45

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'tooth extraction'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:45

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:45

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:18

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:45

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Apr 2021'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:55

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CT Scan'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:55

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:55

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:18

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:28:55

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Apr 2021'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:29:07

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'balloon sinuplasty'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:29:07

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:29:07

US3032108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:18

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 16:29:07

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'USA-US032-2021-MRNA-1273-P301000012'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Yes (Y)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Yes (Y)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Keith'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Vrbicky'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:58:12
User entered 'US'	System	03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 18:35:12
User entered '1'	System	03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'USA-US032-2021-MRNA-1273-P301000012'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Yes (Y)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Yes (Y)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Keith'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Vrbicky'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:58:12
User entered 'US'	System	03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 18:35:12
User entered '1'	System	03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
User entered '03/May/2021 05:57'	(b) (4) System	03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:58:12
User entered 'I'		03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'USA-US032-2021-MRNA-1273-P301000012'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Yes (Y)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Yes (Y)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'No (N)'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Keith'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:57:47
User entered 'Vrbicky'	System	03 May 2021 12:57:23

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 12:58:12
User entered 'US'	System	03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 18:35:12
User entered '1'	System	03 May 2021 12:57:56

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 11:35'	System	03 May 2021 18:35:12

US3032108

Folder: SAE USA-US032-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	03 May 2021 18:35:12