

US3002149 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:50:12

All time stamps listed in this document are displayed in GMT

US3002149

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 13:08:27

Generated On: 09 Jun 2021 14:50:12

Participant ID

US3002149

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

US3002149

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" 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) 13 Feb 2021 13:08:28

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Date of Informed Consent (*dd MMM yyyy*) 11 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 13:08:28

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Condition	PEPTIC ULCER DISEASE
Start date (dd MMM yyyy)	04 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Condition	VANCOMYCIN ALLERGY
Start date (dd MMM yyyy)	UN MAY 2019
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)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Condition	RIGHT LEG AMPUTATION
Start date (dd MMM yyyy)	16 JUL 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	16 JUL 2016
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JUL 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Condition	LEFT LEG AMPUTATION
Start date (dd MMM yyyy)	24 SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	24 SEP 2019
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	SEP 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Condition	CHARCOT-MARIE TOOTH DISORDER
Start date (dd MMM yyyy)	04 MAR 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	24 SEP 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	SEP 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:27 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:27
Height (<i>xxx.x</i>)	193 cm
Weight (<i>xxx.x</i>)	129 kg
BMI (<i>xxx.x</i>)	34.63180 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) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 13:08:28

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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 RUNS ERRANDS, GROCERY SHOPPING, RESTAURANTS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 13:08:28

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

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

What was the participant's randomization number? 102998

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk
 >=18 and <65 years and at risk
 >=65 years

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes No

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes No

Severe obesity (body mass index > or = 40kg/m2) Yes No

Diabetes (Type I, Type 2, or gestational) Yes No

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

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) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:27 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:27
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	96 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:12 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:12
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was study treatment given? Yes
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:37 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 12:37

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) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 11 AUG 2020

Collection time (*00:00-23:59*) 12:10 (24 HR)

Collection date and time (derived) 11 AUG 2020 12:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Collection date (<i>dd MMM yyyy</i>)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:02	11 AUG 2020 12:02
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp 11 AUG 2020 13:19

PC Open Date & Time 11 AUG 2020 12:57

PC Close Date & Time 11 AUG 2020 15:27

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 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):

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

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

PC Time Stamp 11 AUG 2020 20:14

PC Open Date & Time 11 AUG 2020 16:22

PC Close Date & Time 12 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 12:08
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.7 °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):

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

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

PC Time Stamp 13 AUG 2020 18:55

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 14 AUG 2020 18:18

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 98.6 °F

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

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

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

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

PC Time Stamp 15 AUG 2020 14:16

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.7 °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):

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

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

PC Time Stamp 16 AUG 2020 14:00

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.5 °F

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

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

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

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

PC Time Stamp 17 AUG 2020 13:43

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

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 97.5 °F

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

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

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

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

PC Time Stamp 18 AUG 2020 12:18

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 9

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.1 °F

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

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

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

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

PC Time Stamp 19 AUG 2020 12:04

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 10

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):

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

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

PC Time Stamp 20 AUG 2020 12:14

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 11

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 95.7 °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):

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

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

PC Time Stamp 21 AUG 2020 18:49

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 12

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.1 °F

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

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

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

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

PC Time Stamp 22 AUG 2020 15:38

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 13

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 98.2 °F

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

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

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

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

PC Time Stamp 23 AUG 2020 12:43

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 14

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.8 °F

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

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

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

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

PC Time Stamp 24 AUG 2020 13:24

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 15

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):

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

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

PC Time Stamp 25 AUG 2020 15:04

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 16

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

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

PC Time Stamp 26 AUG 2020 16:07

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 17

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

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

PC Time Stamp 27 AUG 2020 17:14

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 18

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):

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

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

PC Time Stamp 28 AUG 2020 14:26

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 19

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):

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

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

PC Time Stamp 29 AUG 2020 12:59

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 20

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.2 °F

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

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

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

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

PC Time Stamp 30 AUG 2020 12:36

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 21

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.7 °F

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

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

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

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

PC Time Stamp 31 AUG 2020 14:02

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 22

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 95.3 °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):

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

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

PC Time Stamp 02 SEP 2020 00:00

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 23

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** 95.9 °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 True

PC Time Stamp 02 SEP 2020 12:29

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 24

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

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

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

PC Time Stamp 03 SEP 2020 12:28

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 25

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):

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

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

PC Time Stamp 04 SEP 2020 19:16

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 26

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 05 SEP 2020 12:18

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 27

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 99.2 °F

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

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

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

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

PC Time Stamp 06 SEP 2020 12:53

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 28

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

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

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

PC Time Stamp 07 SEP 2020 14:54

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 29

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 08 SEP 2020 12:05

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 AUG 2020 13:19

PC Open Date & Time

11 AUG 2020 12:57

PC Close Date & Time

11 AUG 2020 15:27

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 AUG 2020 20:14

PC Open Date & Time

11 AUG 2020 16:22

PC Close Date & Time

12 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	12 AUG 2020 12:09
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 3

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	13 AUG 2020 18:56
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 4

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

14 AUG 2020 18:18

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	15 AUG 2020 14:16
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 6

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

16 AUG 2020 14:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 7

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

17 AUG 2020 13:43

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

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

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

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

No

Yes

PC Time stamp	11 AUG 2020 13:20
PC Open Date & Time	11 AUG 2020 12:57
PC Close Date & Time	11 AUG 2020 15:27

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

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

No

Yes

PC Time stamp	11 AUG 2020 20:15
PC Open Date & Time	11 AUG 2020 16:22
PC Close Date & Time	12 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 2

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

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

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 3

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 18:57
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 4

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	14 AUG 2020 18:19
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 5

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 14:17
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 6

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	16 AUG 2020 14:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 7

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	17 AUG 2020 13:44
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

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

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 12:04
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 12:14
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 18:49
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 15:38
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 12:43
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 AUG 2020 13:24
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 15:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 AUG 2020 16:07
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 17
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	27 AUG 2020 17:14
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 AUG 2020 14:26
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 AUG 2020 12:59
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 12:36
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 14:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 00:00
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 12:29
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 12:28
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 19:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 12:19
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 12:54
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 14:54
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 12:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3002149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

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

US3002149

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 SEP 2020

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

Folder OID VISIT2

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:28 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 10:28
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:40 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 11:40
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3002149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was study treatment given? Yes
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 09 SEP 2020

What was the treatment time? (00:00-23:59) 11:08 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 11:08

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

US3002149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 09 SEP 2020

Collection time (*00:00-23:59*) 10:42 (24 HR)

Collection date and time (derived) 09 SEP 2020 10:42

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Collection date (<i>dd MMM yyyy</i>)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:44	09 SEP 2020 10:44
Nasopharyngeal Swab 2	No		

US3002149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp 09 SEP 2020 11:38

PC Open Date & Time 09 SEP 2020 11:28

PC Close Date & Time 09 SEP 2020 13:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.6 °F

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

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

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

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

PC Time Stamp 09 SEP 2020 14:57

PC Open Date & Time 09 SEP 2020 14:53

PC Close Date & Time 10 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.3 °F

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

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

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

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

PC Time Stamp 10 SEP 2020 12:10

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.0 °F

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

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

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

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

PC Time Stamp 11 SEP 2020 15:00

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.6 °F

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

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

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

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

PC Time Stamp 12 SEP 2020 17:03

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.9 °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 True

PC Time Stamp 13 SEP 2020 15:04

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 95.9 °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 True

PC Time Stamp 14 SEP 2020 16:18

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.5 °F

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

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

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

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

PC Time Stamp 15 SEP 2020 13:12

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):	
To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	16 SEP 2020 19:12
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 9

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.3 °F

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

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

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

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

PC Time Stamp 17 SEP 2020 16:43

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 10

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.5 °F

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

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

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

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

PC Time Stamp 18 SEP 2020 15:31

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 11

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):

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

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

PC Time Stamp 19 SEP 2020 15:41

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 12

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.8 °F

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

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

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

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

PC Time Stamp 20 SEP 2020 16:14

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 13

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.9 °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 False

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

PC Time Stamp 21 SEP 2020 15:02

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 14

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.8 °F

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

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

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

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

PC Time Stamp 22 SEP 2020 15:14

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 15

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 95.3 °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):

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

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

PC Time Stamp 24 SEP 2020 05:24

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 16

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):

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

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

PC Time Stamp 24 SEP 2020 12:53

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 17

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.3 °F

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

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

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

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

PC Time Stamp 25 SEP 2020 17:09

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 18

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 26 SEP 2020 12:40

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 19

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):

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

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

PC Time Stamp 27 SEP 2020 19:45

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 20

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 95.7 °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):

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

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

PC Time Stamp 29 SEP 2020 06:03

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 21

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

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

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

PC Time Stamp 29 SEP 2020 13:40

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 22

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):

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

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

PC Time Stamp 30 SEP 2020 12:31

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 23

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):

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

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

PC Time Stamp 01 OCT 2020 20:05

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 24

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

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

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

PC Time Stamp 02 OCT 2020 18:37

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 25

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 95.9 °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 False

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

PC Time Stamp 03 OCT 2020 15:52

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 26

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.8 °F

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

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

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

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

PC Time Stamp 04 OCT 2020 12:15

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 27

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.7 °F

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

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

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

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

PC Time Stamp 05 OCT 2020 13:30

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 28

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.8 °F

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

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

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

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

PC Time Stamp 06 OCT 2020 21:46

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 29

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 95.1 °F

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

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

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

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

PC Time Stamp 07 OCT 2020 15:34

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 30

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.4 °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):

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

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

PC Time Stamp 08 OCT 2020 13:53

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 31

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 09 OCT 2020 12:42

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 32

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 95.7 °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):

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

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

PC Time Stamp 10 OCT 2020 16:57

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 33

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** 95.0 °F

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

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

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

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

PC Time Stamp 12 OCT 2020 07:34

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 34

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.0 °F

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

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

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

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

PC Time Stamp 12 OCT 2020 15:04

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 35

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.5 °F

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

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

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

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

PC Time Stamp 13 OCT 2020 20:12

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 36

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** 95.5 °F

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

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

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

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

PC Time Stamp 14 OCT 2020 12:52

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 37

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):	
To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	15 OCT 2020 12:11
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 38

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 95.6 °F

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

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

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

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

PC Time Stamp 17 OCT 2020 07:24

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 39

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 17 OCT 2020 19:31

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 40

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.5 °F

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

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

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

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

PC Time Stamp 18 OCT 2020 17:09

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 41

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.2 °F

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

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

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

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

PC Time Stamp 19 OCT 2020 12:13

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 42

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 20 OCT 2020 16:37

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 43

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.9 °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 False

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

PC Time Stamp 21 OCT 2020 12:10

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 44

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** 95.6 °F

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

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

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

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

PC Time Stamp 22 OCT 2020 16:04

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 45

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 23 OCT 2020 20:54

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 46

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

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

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

PC Time Stamp 24 OCT 2020 19:25

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 47

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.9 °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 True

PC Time Stamp 25 OCT 2020 12:18

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 48

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** 95.4 °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):

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

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

PC Time Stamp 26 OCT 2020 12:40

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 49

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** 95.6 °F

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

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

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

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

PC Time Stamp 28 OCT 2020 01:05

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 50

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.3 °F

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

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

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

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

PC Time Stamp 28 OCT 2020 18:38

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 51

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.8 °F

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

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

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

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

PC Time Stamp 29 OCT 2020 17:31

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 52

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.2 °F

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

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

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

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

PC Time Stamp 30 OCT 2020 15:16

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 53

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.7 °F

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

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

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

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

PC Time Stamp 31 OCT 2020 20:42

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 54

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.6 °F

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

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

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

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

PC Time Stamp 01 NOV 2020 12:24

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 55

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 95.7 °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):

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

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

PC Time Stamp 02 NOV 2020 12:12

PC Open Date & Time 02 NOV 2020 12:00

PC Close Date & Time 03 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 56

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.2 °F

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

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

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

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

PC Time Stamp 03 NOV 2020 15:44

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 57

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 04 NOV 2020 12:46

PC Open Date & Time 04 NOV 2020 12:00

PC Close Date & Time 05 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 58

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.7 °F

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

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

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

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

PC Time Stamp 05 NOV 2020 16:47

PC Open Date & Time 05 NOV 2020 12:00

PC Close Date & Time 06 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 59

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.1 °F

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

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

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

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

PC Time Stamp 06 NOV 2020 15:45

PC Open Date & Time 06 NOV 2020 12:00

PC Close Date & Time 07 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 60

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 07 NOV 2020 19:35

PC Open Date & Time 07 NOV 2020 12:00

PC Close Date & Time 08 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 61

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.6 °F

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

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

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

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

PC Time Stamp 08 NOV 2020 19:13

PC Open Date & Time 08 NOV 2020 12:00

PC Close Date & Time 09 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 62

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.6 °F

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

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

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

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

PC Time Stamp 09 NOV 2020 13:49

PC Open Date & Time 09 NOV 2020 12:00

PC Close Date & Time 10 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 63

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.2 °F

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

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

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

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

PC Time Stamp 10 NOV 2020 17:58

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 64

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.7 °F

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

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

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

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

PC Time Stamp 11 NOV 2020 15:57

PC Open Date & Time 11 NOV 2020 12:00

PC Close Date & Time 12 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 65

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

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

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

PC Time Stamp 12 NOV 2020 16:18

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 66

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.6 °F

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

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

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

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

PC Time Stamp 13 NOV 2020 20:11

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 67

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

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

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

PC Time Stamp 14 NOV 2020 14:02

PC Open Date & Time 14 NOV 2020 12:00

PC Close Date & Time 15 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 68

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 15 NOV 2020 12:10

PC Open Date & Time 15 NOV 2020 12:00

PC Close Date & Time 16 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 69

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.

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Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

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

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

PC Time Stamp 16 NOV 2020 12:42

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 70

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 95.8 °F

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

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

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

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

PC Time Stamp 17 NOV 2020 13:21

PC Open Date & Time 17 NOV 2020 12:00

PC Close Date & Time 18 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 71

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 18 NOV 2020 13:46

PC Open Date & Time 18 NOV 2020 12:00

PC Close Date & Time 19 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 72

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

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

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

PC Time Stamp 20 NOV 2020 06:53

PC Open Date & Time 19 NOV 2020 12:00

PC Close Date & Time 20 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 73

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 20 NOV 2020 22:16

PC Open Date & Time 20 NOV 2020 12:00

PC Close Date & Time 21 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 74

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.0 °F

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

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

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

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

PC Time Stamp 21 NOV 2020 21:30

PC Open Date & Time 21 NOV 2020 12:00

PC Close Date & Time 22 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 75

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):

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

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

PC Time Stamp 22 NOV 2020 16:51

PC Open Date & Time 22 NOV 2020 12:00

PC Close Date & Time 23 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 76

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 23 NOV 2020 12:14

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 77

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):

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

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

PC Time Stamp 24 NOV 2020 16:45

PC Open Date & Time 24 NOV 2020 12:00

PC Close Date & Time 25 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 78

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	25 NOV 2020 16:44
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

Is there any **REDNESS AT INJECTION SITE?**

- Yes
- No

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	09 SEP 2020 11:38
PC Open Date & Time	09 SEP 2020 11:28
PC Close Date & Time	09 SEP 2020 13:58

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None

Does not interfere with activity

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity

Any use of prescription pain
reliever or prevents daily activity

Is there any **REDNESS AT INJECTION SITE?**

Yes

No

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes

No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None

Does not interfere with activity

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 SEP 2020 14:57

PC Open Date & Time

09 SEP 2020 14:53

PC Close Date & Time

10 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 2

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

10 SEP 2020 12:11

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

Is there any **REDNESS AT INJECTION SITE?**

- Yes
- No

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	11 SEP 2020 15:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None

Does not interfere with activity

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity

Any use of prescription pain
reliever or prevents daily activity

Is there any **REDNESS AT INJECTION SITE?**

Yes

No

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes

No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None

Does not interfere with activity

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

12 SEP 2020 17:04

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 5

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

13 SEP 2020 15:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 6

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

14 SEP 2020 16:18

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None

Does not interfere with activity

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity

Any use of prescription pain
reliever or prevents daily activity

Is there any **REDNESS AT INJECTION SITE?**

Yes

No

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes

No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None

Does not interfere with activity

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

15 SEP 2020 13:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

No

Yes

PC Time stamp	09 SEP 2020 11:39
PC Open Date & Time	09 SEP 2020 11:28
PC Close Date & Time	09 SEP 2020 13:58

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

No

Yes

PC Time stamp	09 SEP 2020 14:58
PC Open Date & Time	09 SEP 2020 14:53
PC Close Date & Time	10 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 2

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 12:11
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 3

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	11 SEP 2020 15:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 4

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 17:04
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 5

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 15:04
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 6

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 16:18
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 7

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 13:13
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 19:12
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 16:44
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 15:31
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 15:41
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 16:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 SEP 2020 15:02
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 15:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 05:24
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 12:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 17:09
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 12:40
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 SEP 2020 19:45
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 06:03
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 13:40
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 12:31
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 20:06
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 18:37
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 OCT 2020 15:52
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 12:15
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 13:31
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 21:46
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 15:34
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 13:53
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 31
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	09 OCT 2020 12:42
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 16:57
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 33
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 OCT 2020 07:34
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 34
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 OCT 2020 15:04
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 35
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 OCT 2020 20:12
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 36
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 12:52
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 37
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 12:11
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 38
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 07:24
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 39
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 19:31
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 40
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 17:09
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 41
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 OCT 2020 12:14
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 42
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 16:37
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 43
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 12:10
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 44
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 16:04
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 45
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 20:54
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 46
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 OCT 2020 19:25
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 47
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 12:18
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 48
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 12:40
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 49
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 OCT 2020 01:05
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 50
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 OCT 2020 18:38
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 51
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 OCT 2020 17:31
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 52
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 15:17
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 53
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	31 OCT 2020 20:42
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 54
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 NOV 2020 12:24
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 55
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 NOV 2020 12:13
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 56
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 NOV 2020 15:44
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 57
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 NOV 2020 12:47
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 58
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 NOV 2020 16:47
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 59
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 NOV 2020 15:45
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 60
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 NOV 2020 19:36
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 61
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 NOV 2020 19:13
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 62
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 NOV 2020 13:49
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 63
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	10 NOV 2020 17:58
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 64
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 NOV 2020 15:57
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 65
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 NOV 2020 16:18
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 66
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 NOV 2020 20:11
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 67
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 NOV 2020 14:02
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 68
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 NOV 2020 12:10
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 69
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 NOV 2020 12:43
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 70
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 NOV 2020 13:21
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 71
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 NOV 2020 13:46
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 72
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 NOV 2020 06:53
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 73
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 NOV 2020 22:16
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 74
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 NOV 2020 21:30
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 75
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 NOV 2020 16:51
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 76
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 NOV 2020 12:14
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 77
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 NOV 2020 16:46
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 78
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 NOV 2020 16:44
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3002149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

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

US3002149

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 OCT 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:10:19

Generated On: 09 Jun 2021 14:50:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 OCT 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT3

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 13:10:19

Generated On: 09 Jun 2021 14:50:12

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 05 OCT 2020

Time of assessment (*00:00-23:59*) 10:19 (24 HR)

Vital Signs Date and Time (derived) 05 OCT 2020 10:19

Temperature (*xxx.x*) 37.0 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) 96 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 12 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 135 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 90 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3002149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:10:19

Generated On: 09 Jun 2021 14:50:12

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy) _____

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3002149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:10:19

Generated On: 09 Jun 2021 14:50:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 OCT 2020

Collection time (*00:00-23:59*) 10:28 (24 HR)

Collection date and time (derived) 05 OCT 2020 10:28

US3002149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 OCT 2020 05:59:13
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 18 OCT 2020 07:06:04

Patient Cloud Open Date & Time 18 OCT 2020 00:01

Patient Cloud Close Date & Time 22 OCT 2020 23:59

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

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

25 OCT 2020 07:58:36

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

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

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 08 NOV 2020 05:01:24

Patient Cloud Open Date & Time 08 NOV 2020 00:01

Patient Cloud Close Date & Time 12 NOV 2020 23:59

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 99

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 15 NOV 2020 08:40:20

Patient Cloud Open Date & Time 15 NOV 2020 00:01

Patient Cloud Close Date & Time 19 NOV 2020 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission	20 NOV 2020 06:53:26
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 26 NOV 2020 00:04:50

Patient Cloud Open Date & Time 26 NOV 2020 00:01

Patient Cloud Close Date & Time 30 NOV 2020 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 03 DEC 2020 01:45:52

Patient Cloud Open Date & Time 03 DEC 2020 00:01

Patient Cloud Close Date & Time 07 DEC 2020 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 18:28:28
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 17 DEC 2020 00:03:48

Patient Cloud Open Date & Time 17 DEC 2020 00:01

Patient Cloud Close Date & Time 21 DEC 2020 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 24 DEC 2020 07:36:08

Patient Cloud Open Date & Time 24 DEC 2020 00:01

Patient Cloud Close Date & Time 28 DEC 2020 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 17:44:37
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 10:15:43
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 07:47:48
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 21 JAN 2021 07:29:04

Patient Cloud Open Date & Time 21 JAN 2021 00:01

Patient Cloud Close Date & Time 25 JAN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	28 JAN 2021 07:21:46
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 20:48:40
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 08:14:24
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 05:49:10
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 201

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 25 FEB 2021 00:17:13

Patient Cloud Open Date & Time 25 FEB 2021 00:01

Patient Cloud Close Date & Time 01 MAR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 04 MAR 2021 09:00:32

Patient Cloud Open Date & Time 04 MAR 2021 00:01

Patient Cloud Close Date & Time 08 MAR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 07:29:57
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

18 MAR 2021 12:18:05

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 25 MAR 2021 13:27:46

Patient Cloud Open Date & Time 25 MAR 2021 00:01

Patient Cloud Close Date & Time 29 MAR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 236

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 01 APR 2021 09:02:10

Patient Cloud Open Date & Time 01 APR 2021 00:01

Patient Cloud Close Date & Time 05 APR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 00:18:00
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 APR 2021 04:31:17
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 22 APR 2021 06:56:38

Patient Cloud Open Date & Time 22 APR 2021 00:01

Patient Cloud Close Date & Time 26 APR 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 29 APR 2021 06:33:09

Patient Cloud Open Date & Time 29 APR 2021 00:01

Patient Cloud Close Date & Time 03 MAY 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	06 MAY 2021 00:01
Patient Cloud Close Date & Time	10 MAY 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#) 07 JUN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 320

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 341

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 16 AUG 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 404

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 411

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 25 OCT 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2021 00:01
Patient Cloud Close Date & Time	01 NOV 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	04 NOV 2021 00:01
Patient Cloud Close Date & Time	08 NOV 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 460

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 495

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 24 JAN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 07 FEB 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 28 FEB 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2022 00:01
Patient Cloud Close Date & Time	07 MAR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#) 09 MAY 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 06 JUN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 08 AUG 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 740

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	18 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 10 OCT 2022 23:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-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

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3002149

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:50:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 15:22:01

US3002149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 NOV 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 04:42:56

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 07 DEC 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:27

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:08:28

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 JAN 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:08:27

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 04:42:56

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 FEB 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3002149

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 04:42:56

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 04:08:05

Generated On: 09 Jun 2021 14:50:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 04:08:05

Generated On: 09 Jun 2021 14:50:12

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3002149

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 04:08:05

Generated On: 09 Jun 2021 14:50:12

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3002149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 04:08:05

Generated On: 09 Jun 2021 14:50:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	23 FEB 2021
Collection time (<i>00:00-23:59</i>)	16:27 (24 HR)
Collection date and time (derived)	23 FEB 2021 16:27

US3002149

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 04:08:05

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3002149

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) _____

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments _____

If Contact Not Made, please provide Comments _____

US3002149

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3002149

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:50:12

Date of Contact	_____
Time of Contact	_____
Date and Time of Contact (derived)	_____
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3002149

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:50:12

Generate Next COVID-19 Assessment

Yes

No

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:16:27

Generated On: 09 Jun 2021 14:50:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 12:44:50

Generated On: 09 Jun 2021 14:50:12

Date of updated informed consent (*dd MMM yyyy*) 23 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes
No

Under what version of the Protocol was the Participant unblinded? Amendment 5
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 23 FEB 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:16:27

Generated On: 09 Jun 2021 14:50:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 FEB 2021

Collection time (*00:00-23:59*) 16:27 (24 HR)

Collection date and time (derived) 23 FEB 2021 16:27

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:16:27

Generated On: 09 Jun 2021 14:50:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 FEB 2021

Collection time (*00:00 - 23:59*) 16:28

Collection Date and Time (derived) 23 FEB 2021 16:28

US3002149

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

AEID	
Adverse event	HEMATOCHEZIA
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)	09 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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)	_____

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

AEID USA-US005-2021-MRNA-1273-P30
1000011

Adverse event ESOPHAGEAL CANCER

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) 09 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

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

PATIENT GOT CONFIRMED
DIAGNOSIS OF ESOPHAGEAL
CANCER ON 4/19/2021. HE
REPORTED THAT IT IS NOT
OPERABLE AND WAS GIVEN 2-5
MONTHS TO LIVE. MED
RECORD RELEASE FORM
MAILED TO PATIENT FOR
RECORDS.

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)	

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 13:08:27

Generated On: 09 Jun 2021 14:50:12

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Name of Medication PANTOPRAZOLE

Prophylaxis Yes
No

Indication PEPTIC ULCER DISEASE

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 10 JUL 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Name of Medication IBUPORFEN

Prophylaxis Yes
No

Indication BILATERAL LEG AMPUTATION

Dose per administration 800

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Name of Medication SUCRALFATE

Prophylaxis Yes
No

Indication ESOPHAGEAL CANCER

Dose per administration 10000000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 15 APR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication ESOPHAGEAL CANCER

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:24:28

Generated On: 09 Jun 2021 14:50:12

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 15 APR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3002149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 13:08:27

Generated On: 09 Jun 2021 14:50:12

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3002149

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:50:12

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Due to SARS-COV-2

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3002149

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:50:12

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes

No

Unknown

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

SAEID	USA-US005-2021-MRNA-1273-P30 1000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

SAEID	USA-US005-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/APR/2021 11:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

SAEID	USA-US005-2021-MRNA-1273-P30 1000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 14:02
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

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 11:48:55

Generated On: 09 Jun 2021 14:50:12

SAEID	USA-US005-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/APR/2021 11:16
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

US3002149 (Prod: Meridian Clinical Research)

US3002149

Form: Participant Creation

Generated On: 09 Jun 2021 14:50:12

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'US3002149'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:49:37

US3002149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 12:59:29

US3002149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:49:38

US3002149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 12:59:29

US3002149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'SCRN'	System	12 Aug 2020 12:59:29

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit 2 Day 29: Year of Birth (1963) recorded on this form does not match with the Year of birth (1957) reported in PPD Central lab. Please reconcile the correct year and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 05:12:44
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit 2 Day 29: Year of Birth (1963) recorded on this form does not match with the Year of birth (1957) reported in PPD Central lab. Please reconcile the correct year and update if confirmed. Else clarify, thank you.' answered with 'year of birth is 1963' (Site from DM).	Tiffany Nemecek (b) (4)	21 Oct 2020 18:41:59
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit 2 Day 29: Year of Birth (1963) recorded on this form does not match with the Year of birth (1957) reported in PPD Central lab. Please reconcile the correct year and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:59:03
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:49:39

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '57'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'YEARS'	System	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '57'	System	11 Aug 2020 17:47:35

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:27

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:47:35
	(b) (4)	

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Aug 2020'	System	11 Aug 2020 17:47:35

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2020'	System	11 Aug 2020 17:47:35

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Amendment 2 (2)'	Tiffany Nemecek (b) (4)	11 Aug 2020 17:47:35

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:47:35

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:47:35
	(b) (4)	

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:47:35
	(b) (4)	

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:47:35

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:49:38

US3002149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '1'	System	11 Aug 2020 17:47:40

US3002149

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:50:12

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:47:40
	(b) (4)	

US3002149

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:50:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:00:58

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Peptic ulcers and perforation, PT: Peptic ulcer, LLT: Peptic ulcer disease - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 12:07:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 12:07:39
Data point term sent to Coder	System	11 Sep 2020 12:06:11
Coding entries removed.	Brandon Essink (b) (4)	11 Sep 2020 12:06:03
User entered 'PEPTIC ULCER DISEASE' reason for change: Data Entry Error	Brandon Essink (b) (4)	11 Sep 2020 12:06:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Peptic ulcers and perforation, PT: Peptic ulcer, LLT: Peptic ulcer - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 13:03:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 13:03:23
Data point term sent to Coder	System	12 Aug 2020 13:02:17
User entered 'Peptic ulcer'	(b) (4), (b) (6)	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '04 Jul 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Jul 2020'	System	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2020'	System	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered empty.	System	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:12

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered empty.	System	12 Aug 2020 13:01:46

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
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: Allergy to antibiotic - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 09:03:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 09:03:47
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: Allergic reaction to antibiotics - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 13:04:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 13:04:24
Data point term sent to Coder	System	12 Aug 2020 13:03:18
User entered 'Vancomycin allergy'	(b) (4), (b) (6)	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'un May 2019'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'May 2019'	System	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2019'	System	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered empty.	System	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:12

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered empty.	System	12 Aug 2020 13:02:24

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:46:06
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'CHARCOT-MARIE TOOTH DISORDER' (Site from DM).	Brandon Essink (b) (4) (b) (4)	11 Sep 2020 16:32:03
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 23:44:18
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Leg amputation, LLT: Leg amputation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:42:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:42:20
Data point term sent to Coder	System	12 Aug 2020 13:03:18
User entered 'Right leg amputation'	(b) (4), (b) (6)	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '16 Jul 2016'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '16 Jul 2016'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Jul 2016'	System	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2016'	System	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Jul 2016'	System	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:12

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2016'	System	12 Aug 2020 13:03:05

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:45:31
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'CHARCOT-MARIE TOOTH DISORDER' (Site from DM).	Brandon Essink (b) (4) (b) (4)	11 Sep 2020 16:32:17
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 23:44:26
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Leg amputation, LLT: Leg amputation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:18:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:18:26
Data point term sent to Coder	System	12 Aug 2020 13:04:19
User entered 'Left leg amputation'	(b) (4), (b) (6)	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '24 Sep 2019'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '24 Sep 2019'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Sep 2019'	System	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2019'	System	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Sep 2019'	System	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:12

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2019'	System	12 Aug 2020 13:03:30

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User coded data point as SOC: Congenital, familial and genetic disorders, HLT: Peripheral nervous system congenital, HLT: Peripheral nervous system disorders congenital NEC, PT: Hereditary motor and sensory neuropathy, LLT: Charcot-Marie-Tooth disease - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 16:32:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 16:32:40
Data point term sent to Coder	System	11 Sep 2020 16:30:42
Coding entries removed.	Brandon Essink (b) (4)	11 Sep 2020 16:30:03
User entered 'CHARCOT-MARIE TOOTH DISORDER' reason for change: Data Entry Error	Brandon Essink (b) (4)	11 Sep 2020 16:30:03
User coded data point as SOC: Congenital, familial and genetic disorders, HLT: Peripheral nervous system congenital, HLT: Peripheral nervous system disorders congenital NEC, PT: Hereditary motor and sensory neuropathy, LLT: Charcot-Marie-Tooth disease - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 22:17:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 22:17:15
Data point term sent to Coder	System	12 Aug 2020 13:04:19
User entered 'Charco-marie tooth disorder'	(b) (4), (b) (6)	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '04 Mar 2016'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '24 Sep 2019'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Mar 2016'	System	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2016'	System	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'Sep 2019'	System	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:12

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '2019'	System	12 Aug 2020 13:04:06

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11:27'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered '11 Aug 2020 11:27'	System	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '193' cm	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:59
DataPoint set to visible.	System	11 Aug 2020 17:47:40

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '129' kg	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:59
DataPoint set to visible.	System	11 Aug 2020 17:47:40

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
Amendment Manager: User entered '34.63180'	System	16 Sep 2020 23:51:51
User entered '34.6'	System	12 Aug 2020 13:04:59
DataPoint set to visible.	System	11 Aug 2020 17:47:40

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'kg/m2'	System	12 Aug 2020 13:04:59
DataPoint set to visible.	System	11 Aug 2020 17:47:40

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:25:46
User entered '36.8' C	(b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:25:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:25:46
User entered '98'	(b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'bpm'	System	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:25:46
User entered '15'	(b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'breaths/min'	System	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:25:46
User entered '134'	(b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'mmHg'	System	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:25:46
User entered '96'	(b) (4), (b) (6)	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User entered 'mmHg'	System	12 Aug 2020 13:04:59

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31

US3002149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31

US3002149

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:05:18

US3002149

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
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 09:44:02
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 17:55:00
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 13:05:18

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Runs errands, grocery shopping, restaurants'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:47:31
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:38

US3002149

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:53

US3002149

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:53

US3002149

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:06:53

US3002149

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'VISIT1'	System	12 Aug 2020 13:06:53

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:14:57

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:35:59
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:35:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 17:14:57
User entered '102998' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:14:57

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	13 Feb 2021 13:08:28
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:14:57

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:07:34

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:07:34

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:07:34

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:07:34

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:07:34

US3002149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:12

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 05:07:50
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:48:03
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 16:48:00
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:22:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:32:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:26:04
User entered '193' cm	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:26:04
User entered '129' kg	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:26:04
User entered '193' cm	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:26:04
User entered '129' kg	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11:27'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '11 Aug 2020 11:27'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '98'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'bpm'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '15'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'breaths/min'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '134'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'mmHg'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '96'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'mmHg'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:26:04
User entered '193' cm	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 16:26:04
User entered '129' kg	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
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)	13 Aug 2020 10:21:39
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Data correct as entered. ' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:09:12
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).		12 Aug 2020 13:09:00
User entered '13:12'	(b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '11 Aug 2020 13:12'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '86'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'bpm'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '16'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'breaths/min'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '112'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'mmHg'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '78'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'mmHg'	System	12 Aug 2020 13:09:00

US3002149

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:25

US3002149

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:25

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:48:16

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:48:16
	(b) (4)	

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:48:16
	(b) (4)	

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 17:48:16

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:48:16
	(b) (4)	

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '12:37'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:48:16

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '11 Aug 2020 12:37'	System	11 Aug 2020 17:48:16

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 17:48:16

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'ONCE'	System	11 Aug 2020 17:48:16

US3002149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 17:48:16

US3002149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:49

US3002149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:49

US3002149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '12:10'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:09:49

US3002149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '11 Aug 2020 12:10'	System	12 Aug 2020 13:09:49

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (11AUG2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:09:14
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (11AUG2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:01:19
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '12:02'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '11 Aug 2020 12:02'	System	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered empty.	System	12 Aug 2020 13:10:03

US3002149

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:10:10

US3002149

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '1'	System	12 Aug 2020 13:10:10

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:18:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'de48a04a-82d2-4635-80e2-b5dc0745025e'	System	11 Aug 2020 18:19:04
User entered 'Yes (Y)'	System	11 Aug 2020 18:19:04

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:18:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'de48a04a-82d2-4635-80e2-b5dc0745025e' User entered '97.6'	System	11 Aug 2020 18:19:04
	System	11 Aug 2020 18:19:04

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:18:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'de48a04a-82d2-4635-80e2-b5dc0745025e'	System	11 Aug 2020 18:19:04
User entered 'No (N)'	System	11 Aug 2020 18:19:04

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:19:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'de48a04a-82d2-4635-80e2-b5dc0745025e'	System	11 Aug 2020 18:19:04
User entered '11 Aug 2020 13:19'	System	11 Aug 2020 18:19:04

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 12:57'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 15:27'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:13:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6236328f-8de6-427b-a8aa-e7d17781f622'	System	12 Aug 2020 01:14:07
User entered 'Yes (Y)'	System	12 Aug 2020 01:14:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:13:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6236328f-8de6-427b-a8aa-e7d17781f622'	System	12 Aug 2020 01:14:07
User entered '97.7'	System	12 Aug 2020 01:14:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:13:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6236328f-8de6-427b-a8aa-e7d17781f622'	System	12 Aug 2020 01:14:07
User entered 'Yes (Y)'	System	12 Aug 2020 01:14:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:48:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:28:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:13:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6236328f-8de6-427b-a8aa-e7d17781f622'	System	12 Aug 2020 01:14:07
User entered '1'	System	12 Aug 2020 01:14:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:13:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6236328f-8de6-427b-a8aa-e7d17781f622'	System	12 Aug 2020 01:14:07
User entered '0'	System	12 Aug 2020 01:14:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:14:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6236328f-8de6-427b-a8aa-e7d17781f622'	System	12 Aug 2020 01:14:07
User entered '11 Aug 2020 20:14'	System	12 Aug 2020 01:14:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 16:22'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 2'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:06:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4512797e-25f2-48df-87ef-bc27b343e0e4'	System	12 Aug 2020 17:09:19
User entered 'Yes (Y)'	System	12 Aug 2020 17:09:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:08:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4512797e-25f2-48df-87ef-bc27b343e0e4'	System	12 Aug 2020 17:09:19
User entered '97.7'	System	12 Aug 2020 17:09:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:08:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4512797e-25f2-48df-87ef-bc27b343e0e4'	System	12 Aug 2020 17:09:19
User entered 'No (N)'	System	12 Aug 2020 17:09:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:08:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4512797e-25f2-48df-87ef-bc27b343e0e4'	System	12 Aug 2020 17:09:19
User entered '12 Aug 2020 12:08'	System	12 Aug 2020 17:09:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 3'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:54:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c6c48f8-7622-4956-a5ed-3b916e243873'	System	13 Aug 2020 23:55:29
User entered 'Yes (Y)'	System	13 Aug 2020 23:55:29

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:54:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c6c48f8-7622-4956-a5ed-3b916e243873'	System	13 Aug 2020 23:55:29
User entered '97.7'	System	13 Aug 2020 23:55:29

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:54:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c6c48f8-7622-4956-a5ed-3b916e243873'	System	13 Aug 2020 23:55:29
User entered 'Yes (Y)'	System	13 Aug 2020 23:55:29

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:48:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:28:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:55:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c6c48f8-7622-4956-a5ed-3b916e243873'	System	13 Aug 2020 23:55:29
User entered '1'	System	13 Aug 2020 23:55:29

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:55:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c6c48f8-7622-4956-a5ed-3b916e243873'	System	13 Aug 2020 23:55:29
User entered '0'	System	13 Aug 2020 23:55:29

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:55:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c6c48f8-7622-4956-a5ed-3b916e243873'	System	13 Aug 2020 23:55:29
User entered '13 Aug 2020 18:55'	System	13 Aug 2020 23:55:29

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 4'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '45efe150-12f6-4b43-9d3c-247042607efe'	System	14 Aug 2020 23:18:35
User entered 'Yes (Y)'	System	14 Aug 2020 23:18:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '45efe150-12f6-4b43-9d3c-247042607efe' User entered '97.8'	System	14 Aug 2020 23:18:35
	System	14 Aug 2020 23:18:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '45efe150-12f6-4b43-9d3c-247042607efe'	System	14 Aug 2020 23:18:35
User entered 'Yes (Y)'	System	14 Aug 2020 23:18:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:48:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '45efe150-12f6-4b43-9d3c-247042607efe'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:29:10
User entered '1'	System	14 Aug 2020 23:18:35
	System	14 Aug 2020 23:18:35
	System	14 Aug 2020 23:18:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '45efe150-12f6-4b43-9d3c-247042607efe'	System	14 Aug 2020 23:18:35
User entered '0'	System	14 Aug 2020 23:18:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '45efe150-12f6-4b43-9d3c-247042607efe'	System	14 Aug 2020 23:18:35
User entered '14 Aug 2020 18:18'	System	14 Aug 2020 23:18:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 5'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:15:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '025d12c0-c604-4920-9969-3449499a7006'	System	15 Aug 2020 19:16:18
User entered 'Yes (Y)'	System	15 Aug 2020 19:16:18

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:15:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '025d12c0-c604-4920-9969-3449499a7006'	System	15 Aug 2020 19:16:18
User entered '98.6'	System	15 Aug 2020 19:16:18

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '025d12c0-c604-4920-9969-3449499a7006'	System	15 Aug 2020 19:16:18
User entered 'Yes (Y)'	System	15 Aug 2020 19:16:18

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:48:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '025d12c0-c604-4920-9969-3449499a7006'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:29:21
User entered '1'	System	15 Aug 2020 19:16:18
	System	15 Aug 2020 19:16:18
	System	15 Aug 2020 19:16:18

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '025d12c0-c604-4920-9969-3449499a7006'	System	15 Aug 2020 19:16:18
User entered '0'	System	15 Aug 2020 19:16:18

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '025d12c0-c604-4920-9969-3449499a7006'	System	15 Aug 2020 19:16:18
User entered '15 Aug 2020 14:16'	System	15 Aug 2020 19:16:18

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 6'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T13:59:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '735035a5-7bd7-4b96-82ae-11dd4db40923'	System	16 Aug 2020 19:00:28
User entered 'Yes (Y)'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '735035a5-7bd7-4b96-82ae-11dd4db40923'	System	16 Aug 2020 19:00:28
User entered '97.7'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '735035a5-7bd7-4b96-82ae-11dd4db40923'	System	16 Aug 2020 19:00:28
User entered 'Yes (Y)'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '735035a5-7bd7-4b96-82ae-11dd4db40923'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:29:34
User entered '1'	System	16 Aug 2020 19:00:28
	System	16 Aug 2020 19:00:28
	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '735035a5-7bd7-4b96-82ae-11dd4db40923'	System	16 Aug 2020 19:00:28
User entered '0'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '735035a5-7bd7-4b96-82ae-11dd4db40923'	System	16 Aug 2020 19:00:28
User entered '16 Aug 2020 14:00'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 7'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:42:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8e2f1cf-3615-4304-866c-22dc03336156'	System	17 Aug 2020 18:43:34
User entered 'Yes (Y)'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8e2f1cf-3615-4304-866c-22dc03336156'	System	17 Aug 2020 18:43:34
User entered '97.5'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8e2f1cf-3615-4304-866c-22dc03336156'	System	17 Aug 2020 18:43:34
User entered 'Yes (Y)'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8e2f1cf-3615-4304-866c-22dc03336156'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:36:58
User entered '1'	System	17 Aug 2020 18:43:34
	System	17 Aug 2020 18:43:34
	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:06
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:37:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8e2f1cf-3615-4304-866c-22dc03336156'	(b) (4)	
User entered '1'	System	17 Aug 2020 18:43:34
	System	17 Aug 2020 18:43:34
	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8e2f1cf-3615-4304-866c-22dc03336156'	System	17 Aug 2020 18:43:34
User entered '17 Aug 2020 13:43'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	16 Aug 2020 19:00:28
User entered 'Day 8'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:17:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a60db1d-39e0-4ffe-9408-166d53b71db5'	System	18 Aug 2020 17:18:06
User entered 'Yes (Y)'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:17:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a60db1d-39e0-4ffe-9408-166d53b71db5'	System	18 Aug 2020 17:18:06
User entered '97.5'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:17:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a60db1d-39e0-4ffe-9408-166d53b71db5'	System	18 Aug 2020 17:18:06
User entered 'Yes (Y)'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:17:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a60db1d-39e0-4ffe-9408-166d53b71db5'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:37:20
User entered '1'	System	18 Aug 2020 17:18:06
	System	18 Aug 2020 17:18:06
	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:12
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:37:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:17:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a60db1d-39e0-4ffe-9408-166d53b71db5'	(b) (4)	
User entered '1'	System	18 Aug 2020 17:18:06
	System	18 Aug 2020 17:18:06
	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:18:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a60db1d-39e0-4ffe-9408-166d53b71db5'	System	18 Aug 2020 17:18:06
User entered '18 Aug 2020 12:18'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Aug 2020 18:43:34
User entered 'Day 9'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:03:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8932dc6c-75c9-472c-8e1a-c607a1bacf22'	System	19 Aug 2020 17:04:14
User entered 'Yes (Y)'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:03:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8932dc6c-75c9-472c-8e1a-c607a1bacf22'	System	19 Aug 2020 17:04:14
User entered '96.1'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:03:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8932dc6c-75c9-472c-8e1a-c607a1bacf22'	System	19 Aug 2020 17:04:14
User entered 'Yes (Y)'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:37:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:04:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8932dc6c-75c9-472c-8e1a-c607a1bacf22'	System	19 Aug 2020 17:04:14
User entered '1'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 06:16:22
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:04:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8932dc6c-75c9-472c-8e1a-c607a1bacf22'	System	19 Aug 2020 17:04:14
User entered '1'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:04:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8932dc6c-75c9-472c-8e1a-c607a1bacf22'	System	19 Aug 2020 17:04:14
User entered '19 Aug 2020 12:04'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Aug 2020 17:18:06
User entered 'Day 10'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:13:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '187acbe7-a19b-4d22-aa4f-b8266ead5089'	System	20 Aug 2020 17:14:38
User entered 'Yes (Y)'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:14:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '187acbe7-a19b-4d22-aa4f-b8266ead5089'	System	20 Aug 2020 17:14:38
User entered '97.7'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:14:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '187acbe7-a19b-4d22-aa4f-b8266ead5089'	System	20 Aug 2020 17:14:38
User entered 'Yes (Y)'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:45:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:14:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '187acbe7-a19b-4d22-aa4f-b8266ead5089'	System	20 Aug 2020 17:14:38
User entered '1'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:21
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:14:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '187acbe7-a19b-4d22-aa4f-b8266ead5089'	(b) (4)	
User entered '1'	System	20 Aug 2020 17:14:38
	System	20 Aug 2020 17:14:38
	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:14:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '187acbe7-a19b-4d22-aa4f-b8266ead5089'	System	20 Aug 2020 17:14:38
User entered '20 Aug 2020 12:14'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	19 Aug 2020 17:04:14
User entered 'Day 11'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:48:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8dcf9f9-18b8-449c-9ab5-8563d86a9f96'	System	21 Aug 2020 23:49:19
User entered 'Yes (Y)'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:49:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8dcf9f9-18b8-449c-9ab5-8563d86a9f96'	System	21 Aug 2020 23:49:19
User entered '95.7'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:49:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8dcf9f9-18b8-449c-9ab5-8563d86a9f96'	System	21 Aug 2020 23:49:19
User entered 'Yes (Y)'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:49:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8dcf9f9-18b8-449c-9ab5-8563d86a9f96'	System	21 Aug 2020 23:49:19
User entered '0'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:25
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:46:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:49:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8dcf9f9-18b8-449c-9ab5-8563d86a9f96'	(b) (4)	
User entered '1'	System	21 Aug 2020 23:49:19
	System	21 Aug 2020 23:49:19
	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:49:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8dcf9f9-18b8-449c-9ab5-8563d86a9f96'	System	21 Aug 2020 23:49:19
User entered '21 Aug 2020 18:49'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Aug 2020 17:14:38
User entered 'Day 12'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:37:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f79ebc4-3313-4d05-9314-453a0fc4f1fa'	System	22 Aug 2020 20:38:39
User entered 'Yes (Y)'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:38:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f79ebc4-3313-4d05-9314-453a0fc4f1fa'	System	22 Aug 2020 20:38:39
User entered '96.1'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:38:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f79ebc4-3313-4d05-9314-453a0fc4f1fa'	System	22 Aug 2020 20:38:39
User entered 'Yes (Y)'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:38:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f79ebc4-3313-4d05-9314-453a0fc4f1fa'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:50:49
User entered '1'	System	22 Aug 2020 20:38:39
	System	22 Aug 2020 20:38:39
	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:34
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:50:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:38:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f79ebc4-3313-4d05-9314-453a0fc4f1fa'	(b) (4)	
User entered '1'	System	22 Aug 2020 20:38:39
	System	22 Aug 2020 20:38:39
	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:38:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f79ebc4-3313-4d05-9314-453a0fc4f1fa'	System	22 Aug 2020 20:38:39
User entered '22 Aug 2020 15:38'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Aug 2020 23:49:19
User entered 'Day 13'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:41:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7020ca96-d448-4029-9d0d-5edc1a13f313'	System	23 Aug 2020 17:43:07
User entered 'Yes (Y)'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:42:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7020ca96-d448-4029-9d0d-5edc1a13f313'	System	23 Aug 2020 17:43:07
User entered '98.2'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:42:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7020ca96-d448-4029-9d0d-5edc1a13f313'	System	23 Aug 2020 17:43:07
User entered 'Yes (Y)'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:43:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7020ca96-d448-4029-9d0d-5edc1a13f313'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:51:15
User entered '1'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:40
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:51:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:43:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7020ca96-d448-4029-9d0d-5edc1a13f313'	(b) (4)	
User entered '1'	System	23 Aug 2020 17:43:07
	System	23 Aug 2020 17:43:07
	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:43:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7020ca96-d448-4029-9d0d-5edc1a13f313'	System	23 Aug 2020 17:43:07
User entered '23 Aug 2020 12:43'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Aug 2020 20:38:39
User entered 'Day 14'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:22:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe8cfda8-de6a-4ffa-b4d2-958105b42e2b'	System	24 Aug 2020 18:24:14
User entered 'Yes (Y)'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:24:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe8cfda8-de6a-4ffa-b4d2-958105b42e2b'	System	24 Aug 2020 18:24:14
User entered '97.8'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:24:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe8cfda8-de6a-4ffa-b4d2-958105b42e2b'	System	24 Aug 2020 18:24:14
User entered 'Yes (Y)'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:52:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:24:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe8cfda8-de6a-4ffa-b4d2-958105b42e2b'	System	24 Aug 2020 18:24:14
User entered '1'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:44
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:52:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:24:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe8cfda8-de6a-4ffa-b4d2-958105b42e2b'	(b) (4)	
User entered '1'	System	24 Aug 2020 18:24:14
	System	24 Aug 2020 18:24:14
	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:24:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe8cfda8-de6a-4ffa-b4d2-958105b42e2b'	System	24 Aug 2020 18:24:14
User entered '24 Aug 2020 13:24'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	23 Aug 2020 17:43:07
User entered 'Day 15'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:02:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4a176f2-12ac-45a7-b0b1-6d52625731c8'	System	25 Aug 2020 20:04:16
User entered 'Yes (Y)'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:04:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4a176f2-12ac-45a7-b0b1-6d52625731c8'	System	25 Aug 2020 20:04:16
User entered '97.7'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:04:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4a176f2-12ac-45a7-b0b1-6d52625731c8'	System	25 Aug 2020 20:04:16
User entered 'Yes (Y)'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:52:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:04:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4a176f2-12ac-45a7-b0b1-6d52625731c8'	(b) (4)	
User entered '1'	System	25 Aug 2020 20:04:16
	System	25 Aug 2020 20:04:16
	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:52
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:53:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:04:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4a176f2-12ac-45a7-b0b1-6d52625731c8'	(b) (4)	
User entered '1'	System	25 Aug 2020 20:04:16
	System	25 Aug 2020 20:04:16
	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:04:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4a176f2-12ac-45a7-b0b1-6d52625731c8'	System	25 Aug 2020 20:04:16
User entered '25 Aug 2020 15:04'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Aug 2020 18:24:14
User entered 'Day 16'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c30ef2a-a551-4347-8bee-a5bc940e3c09'	System	26 Aug 2020 21:07:35
User entered 'Yes (Y)'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c30ef2a-a551-4347-8bee-a5bc940e3c09'	System	26 Aug 2020 21:07:35
User entered '98.2'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c30ef2a-a551-4347-8bee-a5bc940e3c09'	System	26 Aug 2020 21:07:35
User entered 'Yes (Y)'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c30ef2a-a551-4347-8bee-a5bc940e3c09'	System	26 Aug 2020 21:07:35
User entered '0'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:49:55
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:53:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c30ef2a-a551-4347-8bee-a5bc940e3c09'	(b) (4)	
User entered '1'	System	26 Aug 2020 21:07:35
	System	26 Aug 2020 21:07:35
	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0c30ef2a-a551-4347-8bee-a5bc940e3c09'	System	26 Aug 2020 21:07:35
User entered '26 Aug 2020 16:07'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Aug 2020 20:04:16
User entered 'Day 17'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a88d6690-1cba-4a32-8a07-5fbc59ef2384'	System	27 Aug 2020 22:14:20
User entered 'Yes (Y)'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a88d6690-1cba-4a32-8a07-5fbc59ef2384'	System	27 Aug 2020 22:14:20
User entered '98.2'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a88d6690-1cba-4a32-8a07-5fbc59ef2384'	System	27 Aug 2020 22:14:20
User entered 'Yes (Y)'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a88d6690-1cba-4a32-8a07-5fbc59ef2384'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:53:40
User entered '1'	System	27 Aug 2020 22:14:20
	System	27 Aug 2020 22:14:20
	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:20
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:53:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a88d6690-1cba-4a32-8a07-5fbc59ef2384'	(b) (4)	
User entered '1'	System	27 Aug 2020 22:14:20
	System	27 Aug 2020 22:14:20
	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a88d6690-1cba-4a32-8a07-5fbc59ef2384'	System	27 Aug 2020 22:14:20
User entered '27 Aug 2020 17:14'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	26 Aug 2020 21:07:35
User entered 'Day 18'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd76bc659-2489-4d19-b400-75c4d2143e81'	System	28 Aug 2020 19:26:21
User entered 'Yes (Y)'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd76bc659-2489-4d19-b400-75c4d2143e81'	System	28 Aug 2020 19:26:21
User entered '97.4'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd76bc659-2489-4d19-b400-75c4d2143e81'	System	28 Aug 2020 19:26:21
User entered 'Yes (Y)'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Correted' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd76bc659-2489-4d19-b400-75c4d2143e81'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:54:44
User entered '1'	System	28 Aug 2020 19:26:21
	System	28 Aug 2020 19:26:21
	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:26
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd76bc659-2489-4d19-b400-75c4d2143e81'	(b) (4)	
User entered '1'	System	28 Aug 2020 19:26:21
	System	28 Aug 2020 19:26:21
	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd76bc659-2489-4d19-b400-75c4d2143e81'	System	28 Aug 2020 19:26:21
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	27 Aug 2020 22:14:20
User entered 'Day 19'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:58:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ff331e4-6701-47b8-9fa3-4697f4059e43'	System	29 Aug 2020 17:59:08
User entered 'Yes (Y)'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:58:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ff331e4-6701-47b8-9fa3-4697f4059e43'	System	29 Aug 2020 17:59:08
User entered '98.4'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:59:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ff331e4-6701-47b8-9fa3-4697f4059e43'	System	29 Aug 2020 17:59:08
User entered 'Yes (Y)'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:59:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ff331e4-6701-47b8-9fa3-4697f4059e43'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:55:09
User entered '1'	System	29 Aug 2020 17:59:08
	System	29 Aug 2020 17:59:08
	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:32
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:55:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:59:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ff331e4-6701-47b8-9fa3-4697f4059e43'	(b) (4)	
User entered '1'	System	29 Aug 2020 17:59:08
	System	29 Aug 2020 17:59:08
	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:59:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ff331e4-6701-47b8-9fa3-4697f4059e43'	System	29 Aug 2020 17:59:08
User entered '29 Aug 2020 12:59'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Aug 2020 19:26:21
User entered 'Day 20'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '64003d02-3e58-4ea2-88ac-762f51fe6d6e'	System	30 Aug 2020 17:36:39
User entered 'Yes (Y)'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '64003d02-3e58-4ea2-88ac-762f51fe6d6e'	System	30 Aug 2020 17:36:39
User entered '96.2'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '64003d02-3e58-4ea2-88ac-762f51fe6d6e'	System	30 Aug 2020 17:36:39
User entered 'Yes (Y)'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '64003d02-3e58-4ea2-88ac-762f51fe6d6e'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:55:42
User entered '1'	System	30 Aug 2020 17:36:39
	System	30 Aug 2020 17:36:39
	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:38
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:55:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '64003d02-3e58-4ea2-88ac-762f51fe6d6e'	(b) (4)	
User entered '1'	System	30 Aug 2020 17:36:39
	System	30 Aug 2020 17:36:39
	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '64003d02-3e58-4ea2-88ac-762f51fe6d6e'	System	30 Aug 2020 17:36:39
User entered '30 Aug 2020 12:36'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Aug 2020 17:59:08
User entered 'Day 21'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:01:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bad66987-2c79-4126-b943-f2cf1a9c8b75'	System	31 Aug 2020 19:04:40
User entered 'Yes (Y)'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:01:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bad66987-2c79-4126-b943-f2cf1a9c8b75'	System	31 Aug 2020 19:04:40
User entered '96.7'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:01:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bad66987-2c79-4126-b943-f2cf1a9c8b75'	System	31 Aug 2020 19:04:40
User entered 'Yes (Y)'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:02:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bad66987-2c79-4126-b943-f2cf1a9c8b75'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:56:07
User entered '1'	System	31 Aug 2020 19:04:40
	System	31 Aug 2020 19:04:40
	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:44
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:56:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:02:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bad66987-2c79-4126-b943-f2cf1a9c8b75'	(b) (4)	
User entered '1'	System	31 Aug 2020 19:04:40
	System	31 Aug 2020 19:04:40
	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:02:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bad66987-2c79-4126-b943-f2cf1a9c8b75'	System	31 Aug 2020 19:04:40
User entered '31 Aug 2020 14:02'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	30 Aug 2020 17:36:39
User entered 'Day 22'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-01T23:59:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f32105d1-b29e-48d6-a679-c1cbef4212e2'	System	02 Sep 2020 05:00:06
User entered 'Yes (Y)'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T00:00:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f32105d1-b29e-48d6-a679-c1cbef4212e2'	System	02 Sep 2020 05:00:06
User entered '95.3'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T00:00:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f32105d1-b29e-48d6-a679-c1cbef4212e2'	System	02 Sep 2020 05:00:06
User entered 'Yes (Y)'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T00:00:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f32105d1-b29e-48d6-a679-c1cbef4212e2'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:56:30
User entered '1'	System	02 Sep 2020 05:00:06
	System	02 Sep 2020 05:00:06
	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:50
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:56:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T00:00:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f32105d1-b29e-48d6-a679-c1cbef4212e2'	(b) (4)	
User entered '1'	System	02 Sep 2020 05:00:06
	System	02 Sep 2020 05:00:06
	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T00:00:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f32105d1-b29e-48d6-a679-c1cbef4212e2'	System	02 Sep 2020 05:00:06
User entered '02 Sep 2020 00:00'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	31 Aug 2020 19:04:40
User entered 'Day 23'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:27:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cf55af29-2629-4a64-a83e-fd8be9758faa'	System	02 Sep 2020 17:29:21
User entered 'Yes (Y)'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:29:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cf55af29-2629-4a64-a83e-fd8be9758faa'	System	02 Sep 2020 17:29:21
User entered '95.9'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:29:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cf55af29-2629-4a64-a83e-fd8be9758faa'	System	02 Sep 2020 17:29:21
User entered 'Yes (Y)'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:29:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cf55af29-2629-4a64-a83e-fd8be9758faa'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:57:00
User entered '1'	System	02 Sep 2020 17:29:21
	System	02 Sep 2020 17:29:21
	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:56
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:57:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:29:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cf55af29-2629-4a64-a83e-fd8be9758faa'	(b) (4)	
User entered '1'	System	02 Sep 2020 17:29:21
	System	02 Sep 2020 17:29:21
	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:29:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cf55af29-2629-4a64-a83e-fd8be9758faa'	System	02 Sep 2020 17:29:21
User entered '02 Sep 2020 12:29'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Sep 2020 05:00:06
User entered 'Day 24'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '216aa328-3e73-475b-ab16-b09264a6c88e'	System	03 Sep 2020 17:28:37
User entered 'Yes (Y)'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '216aa328-3e73-475b-ab16-b09264a6c88e'	System	03 Sep 2020 17:28:37
User entered '97.9'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '216aa328-3e73-475b-ab16-b09264a6c88e'	System	03 Sep 2020 17:28:37
User entered 'Yes (Y)'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:50:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '216aa328-3e73-475b-ab16-b09264a6c88e'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:58:39
User entered '1'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:02
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:58:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '216aa328-3e73-475b-ab16-b09264a6c88e'	(b) (4)	
User entered '1'	System	03 Sep 2020 17:28:37
	System	03 Sep 2020 17:28:37
	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '216aa328-3e73-475b-ab16-b09264a6c88e'	System	03 Sep 2020 17:28:37
User entered '03 Sep 2020 12:28'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Sep 2020 17:29:21
User entered 'Day 25'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '094ff928-d7f6-49da-9e18-b5fed1871889'	System	05 Sep 2020 00:16:21
User entered 'Yes (Y)'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '094ff928-d7f6-49da-9e18-b5fed1871889'	System	05 Sep 2020 00:16:21
User entered '98.4'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '094ff928-d7f6-49da-9e18-b5fed1871889'	System	05 Sep 2020 00:16:21
User entered 'Yes (Y)'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '094ff928-d7f6-49da-9e18-b5fed1871889'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:59:02
User entered '1'	System	05 Sep 2020 00:16:21
	System	05 Sep 2020 00:16:21
	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:08
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:59:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '094ff928-d7f6-49da-9e18-b5fed1871889'	(b) (4)	
User entered '1'	System	05 Sep 2020 00:16:21
	System	05 Sep 2020 00:16:21
	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '094ff928-d7f6-49da-9e18-b5fed1871889'	System	05 Sep 2020 00:16:21
User entered '04 Sep 2020 19:16'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	03 Sep 2020 17:28:37
User entered 'Day 26'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:18:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b1d19d6a-35b4-40bf-abf5-b3b99199767e'	System	05 Sep 2020 17:18:52
User entered 'Yes (Y)'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:18:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b1d19d6a-35b4-40bf-abf5-b3b99199767e'	System	05 Sep 2020 17:18:52
User entered '97.8'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:18:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b1d19d6a-35b4-40bf-abf5-b3b99199767e'	System	05 Sep 2020 17:18:52
User entered 'Yes (Y)'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:18:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b1d19d6a-35b4-40bf-abf5-b3b99199767e'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:59:38
User entered '1'	System	05 Sep 2020 17:18:52
	System	05 Sep 2020 17:18:52
	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:14
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:59:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:18:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b1d19d6a-35b4-40bf-abf5-b3b99199767e'	(b) (4)	
User entered '1'	System	05 Sep 2020 17:18:52
	System	05 Sep 2020 17:18:52
	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:18:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b1d19d6a-35b4-40bf-abf5-b3b99199767e'	System	05 Sep 2020 17:18:52
User entered '05 Sep 2020 12:18'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Sep 2020 00:16:21
User entered 'Day 27'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:53:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9e21ed4-8184-41fd-9157-562e79343b6a'	System	06 Sep 2020 17:53:57
User entered 'Yes (Y)'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:53:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9e21ed4-8184-41fd-9157-562e79343b6a'	System	06 Sep 2020 17:53:57
User entered '99.2'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:53:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9e21ed4-8184-41fd-9157-562e79343b6a'	System	06 Sep 2020 17:53:57
User entered 'Yes (Y)'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:53:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9e21ed4-8184-41fd-9157-562e79343b6a'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:16:33
User entered '1'	System	06 Sep 2020 17:53:57
	System	06 Sep 2020 17:53:57
	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:19
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:16:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:53:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9e21ed4-8184-41fd-9157-562e79343b6a'	(b) (4)	
User entered '1'	System	06 Sep 2020 17:53:57
	System	06 Sep 2020 17:53:57
	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:53:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9e21ed4-8184-41fd-9157-562e79343b6a'	System	06 Sep 2020 17:53:57
User entered '06 Sep 2020 12:53'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Sep 2020 17:18:52
User entered 'Day 28'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:53:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92d7586-a945-4f82-a313-24121577b24a'	System	07 Sep 2020 19:54:06
User entered 'Yes (Y)'	System	07 Sep 2020 19:54:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:53:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92d7586-a945-4f82-a313-24121577b24a'	System	07 Sep 2020 19:54:06
User entered '97.6'	System	07 Sep 2020 19:54:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:53:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92d7586-a945-4f82-a313-24121577b24a'	System	07 Sep 2020 19:54:06
User entered 'Yes (Y)'	System	07 Sep 2020 19:54:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:53:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92d7586-a945-4f82-a313-24121577b24a'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:16:49
User entered '1'	System	07 Sep 2020 19:54:06
	System	07 Sep 2020 19:54:06
	System	07 Sep 2020 19:54:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:25
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:53:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92d7586-a945-4f82-a313-24121577b24a'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:16:54
User entered '1'	System	07 Sep 2020 19:54:06
	System	07 Sep 2020 19:54:06
	System	07 Sep 2020 19:54:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:54:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92d7586-a945-4f82-a313-24121577b24a'	System	07 Sep 2020 19:54:06
User entered '07 Sep 2020 14:54'	System	07 Sep 2020 19:54:06

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	06 Sep 2020 17:53:57
User entered 'Day 29'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:04:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e80df91-711a-4585-b3be-fbb24ffaf1ee'	System	08 Sep 2020 17:05:50
User entered 'Yes (Y)'	System	08 Sep 2020 17:05:50

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:05:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e80df91-711a-4585-b3be-fbb24ffaf1ee'	System	08 Sep 2020 17:05:50
User entered '97.2'	System	08 Sep 2020 17:05:50

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:05:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e80df91-711a-4585-b3be-fbb24ffaf1ee'	System	08 Sep 2020 17:05:50
User entered 'Yes (Y)'	System	08 Sep 2020 17:05:50

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:51:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:05:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e80df91-711a-4585-b3be-fbb24ffaf1ee'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:17:05
User entered '1'	System	08 Sep 2020 17:05:50
	System	08 Sep 2020 17:05:50
	System	08 Sep 2020 17:05:50

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:05:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e80df91-711a-4585-b3be-fbb24ffaf1ee'	System	08 Sep 2020 17:05:50
User entered '0'	System	08 Sep 2020 17:05:50

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:05:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e80df91-711a-4585-b3be-fbb24ffaf1ee'	System	08 Sep 2020 17:05:50
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 17:05:50

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:19:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '366c07d4-0fcf-4526-a68f-0e1070933622'	System	11 Aug 2020 18:19:54
User entered 'None (1)'	System	11 Aug 2020 18:19:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:19:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '366c07d4-0fcf-4526-a68f-0e1070933622'	System	11 Aug 2020 18:19:54
User entered 'No (N)'	System	11 Aug 2020 18:19:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:19:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '366c07d4-0fcf-4526-a68f-0e1070933622'	System	11 Aug 2020 18:19:54
User entered 'No (N)'	System	11 Aug 2020 18:19:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:19:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '366c07d4-0fcf-4526-a68f-0e1070933622'	System	11 Aug 2020 18:19:54
User entered 'None (1)'	System	11 Aug 2020 18:19:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:19:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '366c07d4-0fcf-4526-a68f-0e1070933622'	System	11 Aug 2020 18:19:54
User entered '11 Aug 2020 13:19'	System	11 Aug 2020 18:19:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 12:57'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 15:27'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:14:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a89b7cc-881b-4609-9bea-bab1512ea19c'	System	12 Aug 2020 01:14:55
User entered 'None (1)'	System	12 Aug 2020 01:14:55

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:14:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a89b7cc-881b-4609-9bea-bab1512ea19c'	System	12 Aug 2020 01:14:55
User entered 'No (N)'	System	12 Aug 2020 01:14:55

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:14:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a89b7cc-881b-4609-9bea-bab1512ea19c'	System	12 Aug 2020 01:14:55
User entered 'No (N)'	System	12 Aug 2020 01:14:55

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:14:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a89b7cc-881b-4609-9bea-bab1512ea19c'	System	12 Aug 2020 01:14:55
User entered 'None (1)'	System	12 Aug 2020 01:14:55

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:14:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a89b7cc-881b-4609-9bea-bab1512ea19c'	System	12 Aug 2020 01:14:55
User entered '11 Aug 2020 20:14'	System	12 Aug 2020 01:14:55

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 16:22'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 2'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '983a4cd1-16c8-457a-87fa-89815552bfc5'	System	12 Aug 2020 17:09:45
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 17:09:45

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '983a4cd1-16c8-457a-87fa-89815552bfc5'	System	12 Aug 2020 17:09:45
User entered 'No (N)'	System	12 Aug 2020 17:09:45

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Is there any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '983a4cd1-16c8-457a-87fa-89815552bfc5'	System	12 Aug 2020 17:09:45
User entered 'No (N)'	System	12 Aug 2020 17:09:45

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '983a4cd1-16c8-457a-87fa-89815552bfc5'	System	12 Aug 2020 17:09:45
User entered 'None (1)'	System	12 Aug 2020 17:09:45

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '983a4cd1-16c8-457a-87fa-89815552bfc5'	System	12 Aug 2020 17:09:45
User entered '12 Aug 2020 12:09'	System	12 Aug 2020 17:09:45

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 3'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:55:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7a546c98-b26c-4c9d-b58b-f0f09f0e417e'	System	13 Aug 2020 23:56:15
User entered 'None (1)'	System	13 Aug 2020 23:56:15

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:55:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7a546c98-b26c-4c9d-b58b-f0f09f0e417e'	System	13 Aug 2020 23:56:15
User entered 'No (N)'	System	13 Aug 2020 23:56:15

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:55:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7a546c98-b26c-4c9d-b58b-f0f09f0e417e'	System	13 Aug 2020 23:56:15
User entered 'No (N)'	System	13 Aug 2020 23:56:15

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:55:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7a546c98-b26c-4c9d-b58b-f0f09f0e417e'	System	13 Aug 2020 23:56:15
User entered 'None (1)'	System	13 Aug 2020 23:56:15

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7a546c98-b26c-4c9d-b58b-f0f09f0e417e'	System	13 Aug 2020 23:56:15
User entered '13 Aug 2020 18:56'	System	13 Aug 2020 23:56:15

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 4'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a90460ab-9a95-470b-b711-30192603050c'	System	14 Aug 2020 23:19:03
User entered 'None (1)'	System	14 Aug 2020 23:19:03

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a90460ab-9a95-470b-b711-30192603050c'	System	14 Aug 2020 23:19:03
User entered 'No (N)'	System	14 Aug 2020 23:19:03

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a90460ab-9a95-470b-b711-30192603050c'	System	14 Aug 2020 23:19:03
User entered 'No (N)'	System	14 Aug 2020 23:19:03

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a90460ab-9a95-470b-b711-30192603050c'	System	14 Aug 2020 23:19:03
User entered 'None (1)'	System	14 Aug 2020 23:19:03

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:18:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a90460ab-9a95-470b-b711-30192603050c'	System	14 Aug 2020 23:19:03
User entered '14 Aug 2020 18:18'	System	14 Aug 2020 23:19:03

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 5'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'efe72184-e9c5-4b24-85de-17cdc25db306'	System	15 Aug 2020 19:16:47
User entered 'None (1)'	System	15 Aug 2020 19:16:47

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'efe72184-e9c5-4b24-85de-17cdc25db306'	System	15 Aug 2020 19:16:47
User entered 'No (N)'	System	15 Aug 2020 19:16:47

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'efe72184-e9c5-4b24-85de-17cdc25db306'	System	15 Aug 2020 19:16:47
User entered 'No (N)'	System	15 Aug 2020 19:16:47

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'efe72184-e9c5-4b24-85de-17cdc25db306'	System	15 Aug 2020 19:16:47
User entered 'None (1)'	System	15 Aug 2020 19:16:47

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'efe72184-e9c5-4b24-85de-17cdc25db306'	System	15 Aug 2020 19:16:47
User entered '15 Aug 2020 14:16'	System	15 Aug 2020 19:16:47

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 6'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '68ca03f8-be88-4ecb-ae93-836c66023b14'	System	16 Aug 2020 19:00:50
User entered 'None (1)'	System	16 Aug 2020 19:00:50

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '68ca03f8-be88-4ecb-ae93-836c66023b14'	System	16 Aug 2020 19:00:50
User entered 'No (N)'	System	16 Aug 2020 19:00:50

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '68ca03f8-be88-4ecb-ae93-836c66023b14'	System	16 Aug 2020 19:00:50
User entered 'No (N)'	System	16 Aug 2020 19:00:50

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '68ca03f8-be88-4ecb-ae93-836c66023b14'	System	16 Aug 2020 19:00:50
User entered 'None (1)'	System	16 Aug 2020 19:00:50

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '68ca03f8-be88-4ecb-ae93-836c66023b14'	System	16 Aug 2020 19:00:50
User entered '16 Aug 2020 14:00'	System	16 Aug 2020 19:00:50

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 7'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '52ceb24e-74b6-498e-b7b4-4395b840f66c'	System	17 Aug 2020 18:43:54
User entered 'None (1)'	System	17 Aug 2020 18:43:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '52ceb24e-74b6-498e-b7b4-4395b840f66c'	System	17 Aug 2020 18:43:54
User entered 'No (N)'	System	17 Aug 2020 18:43:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '52ceb24e-74b6-498e-b7b4-4395b840f66c'	System	17 Aug 2020 18:43:54
User entered 'No (N)'	System	17 Aug 2020 18:43:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '52ceb24e-74b6-498e-b7b4-4395b840f66c'	System	17 Aug 2020 18:43:54
User entered 'None (1)'	System	17 Aug 2020 18:43:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '52ceb24e-74b6-498e-b7b4-4395b840f66c'	System	17 Aug 2020 18:43:54
User entered '17 Aug 2020 13:43'	System	17 Aug 2020 18:43:54

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered 'None (0)'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered 'None (0)'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered 'None (0)'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered 'None (0)'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered 'None (0)'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered 'None (0)'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered 'No (N)'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T13:20:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f7e12a5-e40e-4df6-ad0c-a245cde1a841'	System	11 Aug 2020 18:20:26
User entered '11 Aug 2020 13:20'	System	11 Aug 2020 18:20:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 12:57'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 15:27'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered 'None (0)'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered 'None (0)'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered 'None (0)'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered 'None (0)'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered 'None (0)'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered 'None (0)'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered 'No (N)'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-11T20:15:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8d1fd9c-7ae3-4cb3-961c-27ed993e9936'	System	12 Aug 2020 01:15:40
User entered '11 Aug 2020 20:15'	System	12 Aug 2020 01:15:40

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Aug 2020 16:22'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 2'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da'	System	12 Aug 2020 17:10:23
User entered 'None (0)'	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da'	System	12 Aug 2020 17:10:23
User entered 'None (0)'	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da'	System	12 Aug 2020 17:10:23
User entered 'None (0)'	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:09:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da'	System	12 Aug 2020 17:10:23
User entered 'None (0)'	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:10:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da'	System	12 Aug 2020 17:10:23
User entered 'None (0)'	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:10:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da'	System	12 Aug 2020 17:10:23
User entered 'None (0)'	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:10:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da'	System	12 Aug 2020 17:10:23
User entered 'No (N)'	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-12T12:10:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e1712b30-8482-47f2-bb87-dbc3454a38da' User entered '12 Aug 2020 12:10'	System	12 Aug 2020 17:10:23
	System	12 Aug 2020 17:10:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 3'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered 'None (0)'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered 'None (0)'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered 'None (0)'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered 'None (0)'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered 'None (0)'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered 'None (0)'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:56:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered 'No (N)'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-13T18:57:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c7a216ff-27c1-45ac-b9d0-aa03741eb4c7'	System	13 Aug 2020 23:57:04
User entered '13 Aug 2020 18:57'	System	13 Aug 2020 23:57:04

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 4'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered 'None (0)'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered 'None (0)'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered 'None (0)'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered 'None (0)'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered 'None (0)'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered 'None (0)'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered 'No (N)'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-14T18:19:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '01302058-d11e-45a4-bb73-9b26c6c467b3'	System	14 Aug 2020 23:19:31
User entered '14 Aug 2020 18:19'	System	14 Aug 2020 23:19:31

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 5'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f'	System	15 Aug 2020 19:17:21
User entered 'None (0)'	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f'	System	15 Aug 2020 19:17:21
User entered 'None (0)'	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:16:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f' User entered 'None (0)'	System	15 Aug 2020 19:17:21
	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:17:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f' User entered 'None (0)'	System	15 Aug 2020 19:17:21
	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:17:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f'	System	15 Aug 2020 19:17:21
User entered 'None (0)'	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:17:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f' User entered 'None (0)'	System	15 Aug 2020 19:17:21
	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:17:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f'	System	15 Aug 2020 19:17:21
User entered 'No (N)'	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-15T14:17:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6a1833f7-1221-4fe9-8c47-e6a8ad19335f'	System	15 Aug 2020 19:17:21
User entered '15 Aug 2020 14:17'	System	15 Aug 2020 19:17:21

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 6'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered 'None (0)'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:00:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered 'None (0)'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:01:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered 'None (0)'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:01:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered 'None (0)'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:01:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered 'None (0)'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:01:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered 'None (0)'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:01:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered 'No (N)'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-16T14:01:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7d8f492c-b784-4ab6-9c07-26930b9103d8'	System	16 Aug 2020 19:01:23
User entered '16 Aug 2020 14:01'	System	16 Aug 2020 19:01:23

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 7'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered 'None (0)'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:43:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered 'None (0)'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:44:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered 'None (0)'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:44:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered 'None (0)'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:44:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered 'None (0)'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:44:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered 'None (0)'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:44:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered 'No (N)'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-17T13:44:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07cd40ec-338e-4ae7-9217-e66c114728f5'	System	17 Aug 2020 18:44:26
User entered '17 Aug 2020 13:44'	System	17 Aug 2020 18:44:26

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	16 Aug 2020 19:00:28
User entered 'Day 8'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:18:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92ca878-2d86-4113-a168-692bf78ce6df'	System	18 Aug 2020 17:18:18
User entered 'No (N)'	System	18 Aug 2020 17:18:18

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-18T12:18:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f92ca878-2d86-4113-a168-692bf78ce6df'	System	18 Aug 2020 17:18:18
User entered '18 Aug 2020 12:18'	System	18 Aug 2020 17:18:18

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 19:00:28

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Aug 2020 18:43:34
User entered 'Day 9'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:04:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cef01cb4-5612-44b2-a4de-e6cc1158fadd'	System	19 Aug 2020 17:04:30
User entered 'No (N)'	System	19 Aug 2020 17:04:30

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-19T12:04:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cef01cb4-5612-44b2-a4de-e6cc1158fadd'	System	19 Aug 2020 17:04:30
User entered '19 Aug 2020 12:04'	System	19 Aug 2020 17:04:30

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:43:34

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Aug 2020 17:18:06
User entered 'Day 10'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:14:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b5630e7-6255-4755-b2d7-339da6861320'	System	20 Aug 2020 17:14:44
User entered 'No (N)'	System	20 Aug 2020 17:14:44

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-20T12:14:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b5630e7-6255-4755-b2d7-339da6861320'	System	20 Aug 2020 17:14:44
User entered '20 Aug 2020 12:14'	System	20 Aug 2020 17:14:44

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:18:06

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	19 Aug 2020 17:04:14
User entered 'Day 11'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:49:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7f204b62-15a9-45b5-a563-6f6bfe675f71'	System	21 Aug 2020 23:49:30
User entered 'No (N)'	System	21 Aug 2020 23:49:30

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-21T18:49:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7f204b62-15a9-45b5-a563-6f6bfe675f71'	System	21 Aug 2020 23:49:30
User entered '21 Aug 2020 18:49'	System	21 Aug 2020 23:49:30

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:04:14

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Aug 2020 17:14:38
User entered 'Day 12'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:38:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '22eccb3d-16d9-4614-91e0-c884065224cb'	System	22 Aug 2020 20:38:56
User entered 'No (N)'	System	22 Aug 2020 20:38:56

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-22T15:38:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '22eccb3d-16d9-4614-91e0-c884065224cb'	System	22 Aug 2020 20:38:56
User entered '22 Aug 2020 15:38'	System	22 Aug 2020 20:38:56

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:14:38

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Aug 2020 23:49:19
User entered 'Day 13'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:43:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '74da5a06-a447-484e-a033-8767f149d45a'	System	23 Aug 2020 17:43:18
User entered 'No (N)'	System	23 Aug 2020 17:43:18

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-23T12:43:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '74da5a06-a447-484e-a033-8767f149d45a'	System	23 Aug 2020 17:43:18
User entered '23 Aug 2020 12:43'	System	23 Aug 2020 17:43:18

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 23:49:19

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Aug 2020 20:38:39
User entered 'Day 14'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:24:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '17d6dbe8-06e2-4cd1-9983-38fd7cdda01f'	System	24 Aug 2020 18:24:23
User entered 'No (N)'	System	24 Aug 2020 18:24:23

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-24T13:24:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '17d6dbe8-06e2-4cd1-9983-38fd7cdda01f'	System	24 Aug 2020 18:24:23
User entered '24 Aug 2020 13:24'	System	24 Aug 2020 18:24:23

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 20:38:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	23 Aug 2020 17:43:07
User entered 'Day 15'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:04:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '711905c3-7d80-4d7b-b40e-b038e6a45142'	System	25 Aug 2020 20:04:25
User entered 'No (N)'	System	25 Aug 2020 20:04:25

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-25T15:04:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '711905c3-7d80-4d7b-b40e-b038e6a45142'	System	25 Aug 2020 20:04:25
User entered '25 Aug 2020 15:04'	System	25 Aug 2020 20:04:25

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 17:43:07

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Aug 2020 18:24:14
User entered 'Day 16'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '680f8fc7-22d4-4fc4-b72c-6bd0b5ce47d7'	System	26 Aug 2020 21:07:39
User entered 'No (N)'	System	26 Aug 2020 21:07:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-26T16:07:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '680f8fc7-22d4-4fc4-b72c-6bd0b5ce47d7'	System	26 Aug 2020 21:07:39
User entered '26 Aug 2020 16:07'	System	26 Aug 2020 21:07:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 18:24:14

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Aug 2020 20:04:16
User entered 'Day 17'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '933ba402-f111-41f7-b417-37c1ea2cafd3'	System	27 Aug 2020 22:14:29
User entered 'No (N)'	System	27 Aug 2020 22:14:29

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-27T17:14:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '933ba402-f111-41f7-b417-37c1ea2cafd3'	System	27 Aug 2020 22:14:29
User entered '27 Aug 2020 17:14'	System	27 Aug 2020 22:14:29

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 20:04:16

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	26 Aug 2020 21:07:35
User entered 'Day 18'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5fc24e46-9f7e-471f-919d-ffa926b396d5'	System	28 Aug 2020 19:26:28
User entered 'No (N)'	System	28 Aug 2020 19:26:28

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-28T14:26:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5fc24e46-9f7e-471f-919d-ffa926b396d5'	System	28 Aug 2020 19:26:28
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 19:26:28

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:07:35

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	27 Aug 2020 22:14:20
User entered 'Day 19'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:59:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '377b45ad-6ccd-470c-b95f-71c9647629b0'	System	29 Aug 2020 17:59:15
User entered 'No (N)'	System	29 Aug 2020 17:59:15

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-29T12:59:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '377b45ad-6ccd-470c-b95f-71c9647629b0'	System	29 Aug 2020 17:59:15
User entered '29 Aug 2020 12:59'	System	29 Aug 2020 17:59:15

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:14:20

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Aug 2020 19:26:21
User entered 'Day 20'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '87c46d9b-0871-43e1-bd6c-c484554b0fa5'	System	30 Aug 2020 17:36:47
User entered 'No (N)'	System	30 Aug 2020 17:36:47

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-30T12:36:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '87c46d9b-0871-43e1-bd6c-c484554b0fa5'	System	30 Aug 2020 17:36:47
User entered '30 Aug 2020 12:36'	System	30 Aug 2020 17:36:47

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:26:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Aug 2020 17:59:08
User entered 'Day 21'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:02:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f2693c6-2827-4f1a-9d82-4325a3d95638'	System	31 Aug 2020 19:04:55
User entered 'No (N)'	System	31 Aug 2020 19:04:55

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-08-31T14:02:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f2693c6-2827-4f1a-9d82-4325a3d95638'	System	31 Aug 2020 19:04:55
User entered '31 Aug 2020 14:02'	System	31 Aug 2020 19:04:55

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:59:08

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	30 Aug 2020 17:36:39
User entered 'Day 22'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T00:00:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b04147b6-2df7-4385-9420-37667db52b6b'	System	02 Sep 2020 05:00:12
User entered 'No (N)'	System	02 Sep 2020 05:00:12

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T00:00:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b04147b6-2df7-4385-9420-37667db52b6b'	System	02 Sep 2020 05:00:12
User entered '02 Sep 2020 00:00'	System	02 Sep 2020 05:00:12

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:36:39

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	31 Aug 2020 19:04:40
User entered 'Day 23'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:29:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '33c55523-e3e7-41ea-ab5d-fdf560d66969'	System	02 Sep 2020 17:29:33
User entered 'No (N)'	System	02 Sep 2020 17:29:33

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-02T12:29:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '33c55523-e3e7-41ea-ab5d-fdf560d66969'	System	02 Sep 2020 17:29:33
User entered '02 Sep 2020 12:29'	System	02 Sep 2020 17:29:33

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:04:40

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Sep 2020 05:00:06
User entered 'Day 24'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '249c1324-ad05-425e-9d1b-64322fe8e2b2'	System	03 Sep 2020 17:28:41
User entered 'No (N)'	System	03 Sep 2020 17:28:41

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-03T12:28:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '249c1324-ad05-425e-9d1b-64322fe8e2b2'	System	03 Sep 2020 17:28:41
User entered '03 Sep 2020 12:28'	System	03 Sep 2020 17:28:41

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 05:00:06

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Sep 2020 17:29:21
User entered 'Day 25'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0f87f197-47a5-4d2c-ba46-c24369e23ee4'	System	05 Sep 2020 00:16:31
User entered 'No (N)'	System	05 Sep 2020 00:16:31

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-04T19:16:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0f87f197-47a5-4d2c-ba46-c24369e23ee4'	System	05 Sep 2020 00:16:31
User entered '04 Sep 2020 19:16'	System	05 Sep 2020 00:16:31

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:29:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	03 Sep 2020 17:28:37
User entered 'Day 26'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:18:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb8b80d1-fc58-4ae0-b79e-1be1f6b39ce4'	System	05 Sep 2020 17:19:02
User entered 'No (N)'	System	05 Sep 2020 17:19:02

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-05T12:19:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb8b80d1-fc58-4ae0-b79e-1be1f6b39ce4'	System	05 Sep 2020 17:19:02
User entered '05 Sep 2020 12:19'	System	05 Sep 2020 17:19:02

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:28:37

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Sep 2020 00:16:21
User entered 'Day 27'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:54:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ea8c8d13-c2f0-419b-b366-ace1ff0b9036'	System	06 Sep 2020 17:54:04
User entered 'No (N)'	System	06 Sep 2020 17:54:04

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-06T12:54:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ea8c8d13-c2f0-419b-b366-ace1ff0b9036'	System	06 Sep 2020 17:54:04
User entered '06 Sep 2020 12:54'	System	06 Sep 2020 17:54:04

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 00:16:21

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Sep 2020 17:18:52
User entered 'Day 28'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:54:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '84d33b7e-8485-479d-bffc-78f96c4cceb4'	System	07 Sep 2020 19:54:13
User entered 'No (N)'	System	07 Sep 2020 19:54:13

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-07T14:54:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '84d33b7e-8485-479d-bffc-78f96c4cceb4'	System	07 Sep 2020 19:54:13
User entered '07 Sep 2020 14:54'	System	07 Sep 2020 19:54:13

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:18:52

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	06 Sep 2020 17:53:57
User entered 'Day 29'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:05:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f17e8d40-56b0-42ad-bb2a-71d21c331523'	System	08 Sep 2020 17:05:54
User entered 'No (N)'	System	08 Sep 2020 17:05:54

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-08T12:05:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f17e8d40-56b0-42ad-bb2a-71d21c331523'	System	08 Sep 2020 17:05:54
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 17:05:54

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:53:57

US3002149

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:53:57

US3002149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:29:58

US3002149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:29:58

US3002149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:29:58

US3002149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:29:58

US3002149

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:30:08

US3002149

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '1'	System	19 Aug 2020 17:30:08

US3002149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:26:57

US3002149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:26:57

US3002149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:26:57

US3002149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:26:57

US3002149

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:27:01

US3002149

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '1'	System	03 Sep 2020 16:27:01

US3002149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:27:14

US3002149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:27:14

US3002149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:27:14

US3002149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:27:14

US3002149

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:27:18

US3002149

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '1'	System	03 Sep 2020 16:27:18

US3002149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:00

US3002149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:00

US3002149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:00

US3002149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'VISIT2'	System	09 Sep 2020 17:55:00

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '10:28'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered '09 Sep 2020 10:28'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '88'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'bpm'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '13'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'breaths/min'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '132'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'mmHg'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '88'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'mmHg'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11:40'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered '09 Sep 2020 11:40'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '86'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'bpm'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'breaths/min'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '128'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'mmHg'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '80'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'mmHg'	System	09 Sep 2020 17:55:46

US3002149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:53

US3002149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:55:53

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) Jessica Satorie (b) (4)	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) Jessica Satorie (b) (4)	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	Jessica Satorie (b) (4)	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '09 Sep 2020'	(b) (4) Jessica Satorie (b) (4)	09 Sep 2020 16:36:15
	(b) (4)	

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '11:08'	(b) (4) Jessica Satorie (b) (4)	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '09 Sep 2020 11:08'	System	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4)	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'ONCE'	System	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:12

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 16:36:15

US3002149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:06

US3002149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:06

US3002149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '10:42'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:06

US3002149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '09 Sep 2020 10:42'	System	09 Sep 2020 17:56:06

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated(09SEP2020) sample recorded in EDC for Visit 2 Day 29, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:09:20
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated(09SEP2020) sample recorded in EDC for Visit 2 Day 29, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:01:34
User entered '09 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '10:44'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '09 Sep 2020 10:44'	System	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered empty.	System	09 Sep 2020 17:56:16

US3002149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:56:20

US3002149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '1'	System	09 Sep 2020 17:56:20

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:37:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '582ff09c-2aa7-42b1-a3c8-c97865bfeb94'	System	09 Sep 2020 16:38:22
User entered 'Yes (Y)'	System	09 Sep 2020 16:38:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:37:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '582ff09c-2aa7-42b1-a3c8-c97865bfeb94'	System	09 Sep 2020 16:38:22
User entered '98.2'	System	09 Sep 2020 16:38:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '582ff09c-2aa7-42b1-a3c8-c97865bfeb94'	System	09 Sep 2020 16:38:22
User entered 'No (N)'	System	09 Sep 2020 16:38:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '582ff09c-2aa7-42b1-a3c8-c97865bfeb94'	System	09 Sep 2020 16:38:22
User entered '09 Sep 2020 11:38'	System	09 Sep 2020 16:38:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 11:28'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 13:58'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0558ae81-23d4-4c3f-8a14-3e7a80b8674d'	System	09 Sep 2020 19:57:22
User entered 'Yes (Y)'	System	09 Sep 2020 19:57:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0558ae81-23d4-4c3f-8a14-3e7a80b8674d'	System	09 Sep 2020 19:57:22
User entered '97.6'	System	09 Sep 2020 19:57:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0558ae81-23d4-4c3f-8a14-3e7a80b8674d'	System	09 Sep 2020 19:57:22
User entered 'Yes (Y)'	System	09 Sep 2020 19:57:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 06:19:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0558ae81-23d4-4c3f-8a14-3e7a80b8674d'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 18:54:41
User entered '1'	System	09 Sep 2020 19:57:22
	System	09 Sep 2020 19:57:22
	System	09 Sep 2020 19:57:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 06:19:29
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 18:54:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0558ae81-23d4-4c3f-8a14-3e7a80b8674d'	(b) (4)	
User entered '1'	System	09 Sep 2020 19:57:22
	System	09 Sep 2020 19:57:22
	System	09 Sep 2020 19:57:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0558ae81-23d4-4c3f-8a14-3e7a80b8674d'	System	09 Sep 2020 19:57:22
User entered '09 Sep 2020 14:57'	System	09 Sep 2020 19:57:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 14:53'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 2'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:10:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '71247cce-410e-4aca-939b-57f95438ab2c'	System	10 Sep 2020 17:10:53
User entered 'Yes (Y)'	System	10 Sep 2020 17:10:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:10:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '71247cce-410e-4aca-939b-57f95438ab2c'	System	10 Sep 2020 17:10:53
User entered '96.3'	System	10 Sep 2020 17:10:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:10:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '71247cce-410e-4aca-939b-57f95438ab2c'	System	10 Sep 2020 17:10:53
User entered 'Yes (Y)'	System	10 Sep 2020 17:10:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:52:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:10:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '71247cce-410e-4aca-939b-57f95438ab2c'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 18:55:00
User entered '1'	System	10 Sep 2020 17:10:53
	System	10 Sep 2020 17:10:53
	System	10 Sep 2020 17:10:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:52:52
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 18:58:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:10:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '71247cce-410e-4aca-939b-57f95438ab2c'	(b) (4)	
User entered '1'	System	10 Sep 2020 17:10:53
	System	10 Sep 2020 17:10:53
	System	10 Sep 2020 17:10:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:10:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '71247cce-410e-4aca-939b-57f95438ab2c'	System	10 Sep 2020 17:10:53
User entered '10 Sep 2020 12:10'	System	10 Sep 2020 17:10:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 3'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:00:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b309615f-948a-4be2-bc57-3b46f4e24259'	System	11 Sep 2020 20:00:57
User entered 'Yes (Y)'	System	11 Sep 2020 20:00:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:00:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b309615f-948a-4be2-bc57-3b46f4e24259'	System	11 Sep 2020 20:00:57
User entered '97.0'	System	11 Sep 2020 20:00:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:00:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b309615f-948a-4be2-bc57-3b46f4e24259'	System	11 Sep 2020 20:00:57
User entered 'Yes (Y)'	System	11 Sep 2020 20:00:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:52:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:00:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b309615f-948a-4be2-bc57-3b46f4e24259'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:22:17
User entered '1'	System	11 Sep 2020 20:00:57
	System	11 Sep 2020 20:00:57
	System	11 Sep 2020 20:00:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:52:57
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:00:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b309615f-948a-4be2-bc57-3b46f4e24259'	(b) (4)	
User entered '1'	System	11 Sep 2020 20:00:57
	System	11 Sep 2020 20:00:57
	System	11 Sep 2020 20:00:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:00:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b309615f-948a-4be2-bc57-3b46f4e24259'	System	11 Sep 2020 20:00:57
User entered '11 Sep 2020 15:00'	System	11 Sep 2020 20:00:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 4'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:03:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ac5fa994-26b1-4541-8d3d-4e487e2ea380'	System	12 Sep 2020 22:03:51
User entered 'Yes (Y)'	System	12 Sep 2020 22:03:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:03:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ac5fa994-26b1-4541-8d3d-4e487e2ea380'	System	12 Sep 2020 22:03:51
User entered '96.6'	System	12 Sep 2020 22:03:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:03:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ac5fa994-26b1-4541-8d3d-4e487e2ea380'	System	12 Sep 2020 22:03:51
User entered 'Yes (Y)'	System	12 Sep 2020 22:03:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:03:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ac5fa994-26b1-4541-8d3d-4e487e2ea380'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:22:32
User entered '1'	System	12 Sep 2020 22:03:51
	System	12 Sep 2020 22:03:51
	System	12 Sep 2020 22:03:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:03
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:22:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:03:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ac5fa994-26b1-4541-8d3d-4e487e2ea380'	(b) (4)	
User entered '1'	System	12 Sep 2020 22:03:51
	System	12 Sep 2020 22:03:51
	System	12 Sep 2020 22:03:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:03:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ac5fa994-26b1-4541-8d3d-4e487e2ea380'	System	12 Sep 2020 22:03:51
User entered '12 Sep 2020 17:03'	System	12 Sep 2020 22:03:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 5'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:03:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2bf431a4-f024-43ea-b0fe-ec7fb70632ba'	System	13 Sep 2020 20:04:16
User entered 'Yes (Y)'	System	13 Sep 2020 20:04:16

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2bf431a4-f024-43ea-b0fe-ec7fb70632ba'	System	13 Sep 2020 20:04:16
User entered '97.9'	System	13 Sep 2020 20:04:16

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2bf431a4-f024-43ea-b0fe-ec7fb70632ba'	System	13 Sep 2020 20:04:16
User entered 'Yes (Y)'	System	13 Sep 2020 20:04:16

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:22:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2bf431a4-f024-43ea-b0fe-ec7fb70632ba'	(b) (4)	
User entered '1'	System	13 Sep 2020 20:04:16
	System	13 Sep 2020 20:04:16
	System	13 Sep 2020 20:04:16

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:09
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:22:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2bf431a4-f024-43ea-b0fe-ec7fb70632ba'	(b) (4)	
User entered '1'	System	13 Sep 2020 20:04:16
	System	13 Sep 2020 20:04:16
	System	13 Sep 2020 20:04:16

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2bf431a4-f024-43ea-b0fe-ec7fb70632ba' User entered '13 Sep 2020 15:04'	System	13 Sep 2020 20:04:16
	System	13 Sep 2020 20:04:16

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 6'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:17:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b7860b9-2cb4-4f20-a265-423215781613'	System	14 Sep 2020 21:18:21
User entered 'Yes (Y)'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b7860b9-2cb4-4f20-a265-423215781613'	System	14 Sep 2020 21:18:21
User entered '95.9'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b7860b9-2cb4-4f20-a265-423215781613'	System	14 Sep 2020 21:18:21
User entered 'Yes (Y)'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:14
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b7860b9-2cb4-4f20-a265-423215781613'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:23:04
User entered '1'	System	14 Sep 2020 21:18:21
	System	14 Sep 2020 21:18:21
	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:16
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:23:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b7860b9-2cb4-4f20-a265-423215781613'	(b) (4)	
User entered '1'	System	14 Sep 2020 21:18:21
	System	14 Sep 2020 21:18:21
	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6b7860b9-2cb4-4f20-a265-423215781613'	System	14 Sep 2020 21:18:21
User entered '14 Sep 2020 16:18'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 7'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75c4ce37-6f9d-4b84-8a1b-4b8efbea8608'	System	15 Sep 2020 18:12:24
User entered 'Yes (Y)'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75c4ce37-6f9d-4b84-8a1b-4b8efbea8608'	System	15 Sep 2020 18:12:24
User entered '96.5'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75c4ce37-6f9d-4b84-8a1b-4b8efbea8608'	System	15 Sep 2020 18:12:24
User entered 'Yes (Y)'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75c4ce37-6f9d-4b84-8a1b-4b8efbea8608'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:23:38
User entered '1'	System	15 Sep 2020 18:12:24
	System	15 Sep 2020 18:12:24
	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:22
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:23:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75c4ce37-6f9d-4b84-8a1b-4b8efbea8608'	(b) (4)	
User entered '1'	System	15 Sep 2020 18:12:24
	System	15 Sep 2020 18:12:24
	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75c4ce37-6f9d-4b84-8a1b-4b8efbea8608'	System	15 Sep 2020 18:12:24
User entered '15 Sep 2020 13:12'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Sep 2020 21:18:21
User entered 'Day 8'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6549b7c7-b71a-46db-8231-8c5d65764013'	System	17 Sep 2020 00:12:56
User entered 'Yes (Y)'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6549b7c7-b71a-46db-8231-8c5d65764013'	System	17 Sep 2020 00:12:56
User entered '98.2'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6549b7c7-b71a-46db-8231-8c5d65764013'	System	17 Sep 2020 00:12:56
User entered 'Yes (Y)'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6549b7c7-b71a-46db-8231-8c5d65764013'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:23:55
User entered '1'	System	17 Sep 2020 00:12:56
	System	17 Sep 2020 00:12:56
	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:27
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:23:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6549b7c7-b71a-46db-8231-8c5d65764013'	System	17 Sep 2020 00:12:56
User entered '1'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6549b7c7-b71a-46db-8231-8c5d65764013'	System	17 Sep 2020 00:12:56
User entered '16 Sep 2020 19:12'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	15 Sep 2020 18:12:24
User entered 'Day 9'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:43:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96eec5a9-172a-4abe-add8-1df3180e936b'	System	17 Sep 2020 21:43:58
User entered 'Yes (Y)'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:43:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96eec5a9-172a-4abe-add8-1df3180e936b'	System	17 Sep 2020 21:43:58
User entered '96.3'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:43:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96eec5a9-172a-4abe-add8-1df3180e936b'	System	17 Sep 2020 21:43:58
User entered 'Yes (Y)'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:31
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:43:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96eec5a9-172a-4abe-add8-1df3180e936b'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 19:24:10
User entered '1'	System	17 Sep 2020 21:43:58
	System	17 Sep 2020 21:43:58
	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:33
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 19:24:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:43:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96eec5a9-172a-4abe-add8-1df3180e936b'	(b) (4)	
User entered '1'	System	17 Sep 2020 21:43:58
	System	17 Sep 2020 21:43:58
	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:43:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96eec5a9-172a-4abe-add8-1df3180e936b'	System	17 Sep 2020 21:43:58
User entered '17 Sep 2020 16:43'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Sep 2020 00:12:56
User entered 'Day 10'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4a72eb21-2d93-4876-a74c-036f51650768'	System	18 Sep 2020 20:31:44
User entered 'Yes (Y)'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4a72eb21-2d93-4876-a74c-036f51650768'	System	18 Sep 2020 20:31:44
User entered '96.5'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4a72eb21-2d93-4876-a74c-036f51650768'	System	18 Sep 2020 20:31:44
User entered 'Yes (Y)'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4a72eb21-2d93-4876-a74c-036f51650768'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:05:13
User entered '1'	System	18 Sep 2020 20:31:44
	System	18 Sep 2020 20:31:44
	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:39
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:05:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4a72eb21-2d93-4876-a74c-036f51650768'	System	18 Sep 2020 20:31:44
User entered '1'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4a72eb21-2d93-4876-a74c-036f51650768'	System	18 Sep 2020 20:31:44
User entered '18 Sep 2020 15:31'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Sep 2020 21:43:58
User entered 'Day 11'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ebc461-fa97-4868-8c1f-f32cb3a9c2ed'	System	19 Sep 2020 20:41:24
User entered 'Yes (Y)'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ebc461-fa97-4868-8c1f-f32cb3a9c2ed'	System	19 Sep 2020 20:41:24
User entered '97.4'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ebc461-fa97-4868-8c1f-f32cb3a9c2ed'	System	19 Sep 2020 20:41:24
User entered 'Yes (Y)'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ebc461-fa97-4868-8c1f-f32cb3a9c2ed'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:05:30
User entered '1'	System	19 Sep 2020 20:41:24
	System	19 Sep 2020 20:41:24
	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:45
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:05:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ebc461-fa97-4868-8c1f-f32cb3a9c2ed'	(b) (4)	
User entered '1'	System	19 Sep 2020 20:41:24
	System	19 Sep 2020 20:41:24
	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ebc461-fa97-4868-8c1f-f32cb3a9c2ed'	System	19 Sep 2020 20:41:24
User entered '19 Sep 2020 15:41'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Sep 2020 20:31:44
User entered 'Day 12'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:14:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd998a705-d417-4a9d-9957-ccb1cf6b97c9'	System	20 Sep 2020 21:14:58
User entered 'Yes (Y)'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:14:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd998a705-d417-4a9d-9957-ccb1cf6b97c9'	System	20 Sep 2020 21:14:58
User entered '96.8'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:14:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd998a705-d417-4a9d-9957-ccb1cf6b97c9'	System	20 Sep 2020 21:14:58
User entered 'Yes (Y)'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:14:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd998a705-d417-4a9d-9957-ccb1cf6b97c9'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:05:49
User entered '1'	System	20 Sep 2020 21:14:58
	System	20 Sep 2020 21:14:58
	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:51
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:05:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:14:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd998a705-d417-4a9d-9957-ccb1cf6b97c9'	(b) (4)	
User entered '1'	System	20 Sep 2020 21:14:58
	System	20 Sep 2020 21:14:58
	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:14:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd998a705-d417-4a9d-9957-ccb1cf6b97c9'	System	20 Sep 2020 21:14:58
User entered '20 Sep 2020 16:14'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	19 Sep 2020 20:41:24
User entered 'Day 13'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4abd8d46-f4c0-4c65-9911-15948389cc85'	System	21 Sep 2020 20:02:36
User entered 'Yes (Y)'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4abd8d46-f4c0-4c65-9911-15948389cc85'	System	21 Sep 2020 20:02:36
User entered '96.9'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4abd8d46-f4c0-4c65-9911-15948389cc85'	System	21 Sep 2020 20:02:36
User entered 'Yes (Y)'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4abd8d46-f4c0-4c65-9911-15948389cc85'	System	21 Sep 2020 20:02:36
User entered '0'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:55
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4abd8d46-f4c0-4c65-9911-15948389cc85'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:06:06
User entered '1'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4abd8d46-f4c0-4c65-9911-15948389cc85'	System	21 Sep 2020 20:02:36
User entered '21 Sep 2020 15:02'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Sep 2020 21:14:58
User entered 'Day 14'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '89193af1-703c-4a5d-b5cb-910ec536531f'	System	22 Sep 2020 20:14:19
User entered 'Yes (Y)'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '89193af1-703c-4a5d-b5cb-910ec536531f' User entered '96.8'	System	22 Sep 2020 20:14:19
	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '89193af1-703c-4a5d-b5cb-910ec536531f'	System	22 Sep 2020 20:14:19
User entered 'Yes (Y)'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:53:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '89193af1-703c-4a5d-b5cb-910ec536531f'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:17:34
User entered '1'	System	22 Sep 2020 20:14:19
	System	22 Sep 2020 20:14:19
	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:01
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:17:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '89193af1-703c-4a5d-b5cb-910ec536531f'	(b) (4)	
User entered '1'	System	22 Sep 2020 20:14:19
	System	22 Sep 2020 20:14:19
	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '89193af1-703c-4a5d-b5cb-910ec536531f'	System	22 Sep 2020 20:14:19
User entered '22 Sep 2020 15:14'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Sep 2020 20:02:36
User entered 'Day 15'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:23:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e747f11b-1da6-449c-928c-bcfb7c269ce5'	System	24 Sep 2020 10:24:50
User entered 'Yes (Y)'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:24:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e747f11b-1da6-449c-928c-bcfb7c269ce5'	System	24 Sep 2020 10:24:50
User entered '95.3'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:24:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e747f11b-1da6-449c-928c-bcfb7c269ce5'	System	24 Sep 2020 10:24:50
User entered 'Yes (Y)'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:24:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e747f11b-1da6-449c-928c-bcfb7c269ce5'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:19:55
User entered '1'	System	24 Sep 2020 10:24:50
	System	24 Sep 2020 10:24:50
	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:06
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:24:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e747f11b-1da6-449c-928c-bcfb7c269ce5'	(b) (4)	
User entered '1'	System	24 Sep 2020 10:24:50
	System	24 Sep 2020 10:24:50
	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:24:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e747f11b-1da6-449c-928c-bcfb7c269ce5'	System	24 Sep 2020 10:24:50
User entered '24 Sep 2020 05:24'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Sep 2020 20:14:19
User entered 'Day 16'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f9efc497-2d2f-4313-ae40-f4748396baaa'	System	24 Sep 2020 17:53:26
User entered 'Yes (Y)'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f9efc497-2d2f-4313-ae40-f4748396baaa'	System	24 Sep 2020 17:53:26
User entered '97.4'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f9efc497-2d2f-4313-ae40-f4748396baaa'	System	24 Sep 2020 17:53:26
User entered 'Yes (Y)'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f9efc497-2d2f-4313-ae40-f4748396baaa'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:20:10
User entered '1'	System	24 Sep 2020 17:53:26
	System	24 Sep 2020 17:53:26
	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:13
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:20:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f9efc497-2d2f-4313-ae40-f4748396baaa'	(b) (4)	
User entered '1'	System	24 Sep 2020 17:53:26
	System	24 Sep 2020 17:53:26
	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f9efc497-2d2f-4313-ae40-f4748396baaa'	System	24 Sep 2020 17:53:26
User entered '24 Sep 2020 12:53'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Sep 2020 10:24:50
User entered 'Day 17'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:08:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2987da6c-d3c1-404b-8cc4-69f7303401ae'	System	25 Sep 2020 22:09:07
User entered 'Yes (Y)'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:08:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2987da6c-d3c1-404b-8cc4-69f7303401ae'	System	25 Sep 2020 22:09:07
User entered '96.3'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:08:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2987da6c-d3c1-404b-8cc4-69f7303401ae'	System	25 Sep 2020 22:09:07
User entered 'Yes (Y)'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:20:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:08:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2987da6c-d3c1-404b-8cc4-69f7303401ae'	System	25 Sep 2020 22:09:07
User entered '1'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:19
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:20:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:08:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2987da6c-d3c1-404b-8cc4-69f7303401ae'	(b) (4)	
User entered '1'	System	25 Sep 2020 22:09:07
	System	25 Sep 2020 22:09:07
	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:09:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2987da6c-d3c1-404b-8cc4-69f7303401ae' User entered '25 Sep 2020 17:09'	System	25 Sep 2020 22:09:07
	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Sep 2020 17:53:26
User entered 'Day 18'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b5a28254-a62f-4438-893b-8c1516480f3d'	System	26 Sep 2020 17:40:46
User entered 'Yes (Y)'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b5a28254-a62f-4438-893b-8c1516480f3d'	System	26 Sep 2020 17:40:46
User entered '97.2'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b5a28254-a62f-4438-893b-8c1516480f3d'	System	26 Sep 2020 17:40:46
User entered 'Yes (Y)'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b5a28254-a62f-4438-893b-8c1516480f3d'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:21:31
User entered '1'	System	26 Sep 2020 17:40:46
	System	26 Sep 2020 17:40:46
	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:25
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:21:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b5a28254-a62f-4438-893b-8c1516480f3d'	(b) (4)	
User entered '1'	System	26 Sep 2020 17:40:46
	System	26 Sep 2020 17:40:46
	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b5a28254-a62f-4438-893b-8c1516480f3d'	System	26 Sep 2020 17:40:46
User entered '26 Sep 2020 12:40'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Sep 2020 22:09:07
User entered 'Day 19'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6eb0c648-be80-40e1-ba72-468d246b020d'	System	28 Sep 2020 00:45:53
User entered 'Yes (Y)'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6eb0c648-be80-40e1-ba72-468d246b020d' User entered '97.3'	System	28 Sep 2020 00:45:53
	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6eb0c648-be80-40e1-ba72-468d246b020d'	System	28 Sep 2020 00:45:53
User entered 'Yes (Y)'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6eb0c648-be80-40e1-ba72-468d246b020d'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:26:33
User entered '1'	System	28 Sep 2020 00:45:53
	System	28 Sep 2020 00:45:53
	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:31
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:26:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6eb0c648-be80-40e1-ba72-468d246b020d'	(b) (4)	
User entered '1'	System	28 Sep 2020 00:45:53
	System	28 Sep 2020 00:45:53
	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6eb0c648-be80-40e1-ba72-468d246b020d' User entered '27 Sep 2020 19:45'	System	28 Sep 2020 00:45:53
	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	26 Sep 2020 17:40:46
User entered 'Day 20'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16dfb625-eaf6-4f89-8c2d-37c97060ac77'	System	29 Sep 2020 11:03:37
User entered 'Yes (Y)'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16dfb625-eaf6-4f89-8c2d-37c97060ac77'	System	29 Sep 2020 11:03:37
User entered '95.7'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16dfb625-eaf6-4f89-8c2d-37c97060ac77'	System	29 Sep 2020 11:03:37
User entered 'Yes (Y)'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16dfb625-eaf6-4f89-8c2d-37c97060ac77'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:27:02
User entered '1'	System	29 Sep 2020 11:03:37
	System	29 Sep 2020 11:03:37
	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:37
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:27:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16dfb625-eaf6-4f89-8c2d-37c97060ac77'	(b) (4)	
User entered '1'	System	29 Sep 2020 11:03:37
	System	29 Sep 2020 11:03:37
	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16dfb625-eaf6-4f89-8c2d-37c97060ac77'	System	29 Sep 2020 11:03:37
User entered '29 Sep 2020 06:03'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Sep 2020 00:45:53
User entered 'Day 21'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8da2f884-36a9-4ec4-81e9-d942a5aea4f6'	System	29 Sep 2020 18:40:50
User entered 'Yes (Y)'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8da2f884-36a9-4ec4-81e9-d942a5aea4f6'	System	29 Sep 2020 18:40:50
User entered '98.1'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8da2f884-36a9-4ec4-81e9-d942a5aea4f6'	System	29 Sep 2020 18:40:50
User entered 'Yes (Y)'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8da2f884-36a9-4ec4-81e9-d942a5aea4f6'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:27:19
User entered '1'	System	29 Sep 2020 18:40:50
	System	29 Sep 2020 18:40:50
	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:42
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:27:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8da2f884-36a9-4ec4-81e9-d942a5aea4f6'	(b) (4)	
User entered '1'	System	29 Sep 2020 18:40:50
	System	29 Sep 2020 18:40:50
	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8da2f884-36a9-4ec4-81e9-d942a5aea4f6'	System	29 Sep 2020 18:40:50
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Sep 2020 11:03:37
User entered 'Day 22'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd3caf64f-5c51-4f3c-98a5-26d0b8a222dc'	System	30 Sep 2020 17:32:12
User entered 'Yes (Y)'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd3caf64f-5c51-4f3c-98a5-26d0b8a222dc'	System	30 Sep 2020 17:32:12
User entered '98.3'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd3caf64f-5c51-4f3c-98a5-26d0b8a222dc'	System	30 Sep 2020 17:32:12
User entered 'Yes (Y)'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:27:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd3caf64f-5c51-4f3c-98a5-26d0b8a222dc'	(b) (4)	
User entered '1'	System	30 Sep 2020 17:32:12
	System	30 Sep 2020 17:32:12
	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:48
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:27:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd3caf64f-5c51-4f3c-98a5-26d0b8a222dc'	(b) (4)	
User entered '1'	System	30 Sep 2020 17:32:12
	System	30 Sep 2020 17:32:12
	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd3caf64f-5c51-4f3c-98a5-26d0b8a222dc'	System	30 Sep 2020 17:32:12
User entered '30 Sep 2020 12:31'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Sep 2020 18:40:50
User entered 'Day 23'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:05:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ff861dbc-23a7-4558-ab03-b41cf0bb3757'	System	02 Oct 2020 01:05:54
User entered 'Yes (Y)'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:05:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ff861dbc-23a7-4558-ab03-b41cf0bb3757'	System	02 Oct 2020 01:05:54
User entered '97.7'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:05:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ff861dbc-23a7-4558-ab03-b41cf0bb3757'	System	02 Oct 2020 01:05:54
User entered 'Yes (Y)'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:05:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ff861dbc-23a7-4558-ab03-b41cf0bb3757'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:27:48
User entered '1'	System	02 Oct 2020 01:05:54
	System	02 Oct 2020 01:05:54
	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:05:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ff861dbc-23a7-4558-ab03-b41cf0bb3757'	System	02 Oct 2020 01:05:54
User entered '0'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:05:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ff861dbc-23a7-4558-ab03-b41cf0bb3757'	System	02 Oct 2020 01:05:54
User entered '01 Oct 2020 20:05'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	30 Sep 2020 17:32:12
User entered 'Day 24'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:36:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '493c9715-1d28-4d8e-8ff9-7821dfe97881'	System	02 Oct 2020 23:37:00
User entered 'Yes (Y)'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:36:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '493c9715-1d28-4d8e-8ff9-7821dfe97881'	System	02 Oct 2020 23:37:00
User entered '98.1'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:36:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '493c9715-1d28-4d8e-8ff9-7821dfe97881'	System	02 Oct 2020 23:37:00
User entered 'Yes (Y)'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:36:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '493c9715-1d28-4d8e-8ff9-7821dfe97881'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:28:44
User entered '1'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:54:58
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:36:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '493c9715-1d28-4d8e-8ff9-7821dfe97881'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:28:49
User entered '1'	System	02 Oct 2020 23:37:00
	System	02 Oct 2020 23:37:00
	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:37:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '493c9715-1d28-4d8e-8ff9-7821dfe97881'	System	02 Oct 2020 23:37:00
User entered '02 Oct 2020 18:37'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Oct 2020 01:05:54
User entered 'Day 25'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '78b1f886-4cfe-4a46-acea-984d9091296a'	System	03 Oct 2020 20:52:40
User entered 'Yes (Y)'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '78b1f886-4cfe-4a46-acea-984d9091296a'	System	03 Oct 2020 20:52:40
User entered '95.9'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '78b1f886-4cfe-4a46-acea-984d9091296a'	System	03 Oct 2020 20:52:40
User entered 'Yes (Y)'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '78b1f886-4cfe-4a46-acea-984d9091296a'	System	03 Oct 2020 20:52:40
User entered '0'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:01
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:29:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '78b1f886-4cfe-4a46-acea-984d9091296a'	(b) (4)	
User entered '1'	System	03 Oct 2020 20:52:40
	System	03 Oct 2020 20:52:40
	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '78b1f886-4cfe-4a46-acea-984d9091296a'	System	03 Oct 2020 20:52:40
User entered '03 Oct 2020 15:52'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Oct 2020 23:37:00
User entered 'Day 26'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3d2de7da-cd5f-49e8-9300-97200ac2cff6'	System	04 Oct 2020 17:15:54
User entered 'Yes (Y)'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3d2de7da-cd5f-49e8-9300-97200ac2cff6'	System	04 Oct 2020 17:15:54
User entered '96.8'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3d2de7da-cd5f-49e8-9300-97200ac2cff6'	System	04 Oct 2020 17:15:54
User entered 'Yes (Y)'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3d2de7da-cd5f-49e8-9300-97200ac2cff6'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:29:15
User entered '1'	System	04 Oct 2020 17:15:54
	System	04 Oct 2020 17:15:54
	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:07
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3d2de7da-cd5f-49e8-9300-97200ac2cff6'	(b) (4)	
User entered '1'	System	04 Oct 2020 17:15:54
	System	04 Oct 2020 17:15:54
	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3d2de7da-cd5f-49e8-9300-97200ac2cff6'	System	04 Oct 2020 17:15:54
User entered '04 Oct 2020 12:15'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	03 Oct 2020 20:52:40
User entered 'Day 27'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:30:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e26ba8e-cee1-49cb-91ab-c9d6c1030986'	System	05 Oct 2020 18:30:59
User entered 'Yes (Y)'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:30:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e26ba8e-cee1-49cb-91ab-c9d6c1030986'	System	05 Oct 2020 18:30:59
User entered '96.7'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:30:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e26ba8e-cee1-49cb-91ab-c9d6c1030986'	System	05 Oct 2020 18:30:59
User entered 'Yes (Y)'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:30:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e26ba8e-cee1-49cb-91ab-c9d6c1030986'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:29:31
User entered '1'	System	05 Oct 2020 18:30:59
	System	05 Oct 2020 18:30:59
	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:12
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:29:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:30:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e26ba8e-cee1-49cb-91ab-c9d6c1030986'	System	05 Oct 2020 18:30:59
User entered '1'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:30:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3e26ba8e-cee1-49cb-91ab-c9d6c1030986'	System	05 Oct 2020 18:30:59
User entered '05 Oct 2020 13:30'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	04 Oct 2020 17:15:54
User entered 'Day 28'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:45:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f65fb049-fada-4dbb-99be-c3f0cccd4eb4'	System	07 Oct 2020 02:46:15
User entered 'Yes (Y)'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:46:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f65fb049-fada-4dbb-99be-c3f0cccd4eb4'	System	07 Oct 2020 02:46:15
User entered '96.8'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:46:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f65fb049-fada-4dbb-99be-c3f0cccd4eb4'	System	07 Oct 2020 02:46:15
User entered 'Yes (Y)'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:46:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f65fb049-fada-4dbb-99be-c3f0cccd4eb4'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:29:47
User entered '1'	System	07 Oct 2020 02:46:15
	System	07 Oct 2020 02:46:15
	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:23
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:29:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:46:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f65fb049-fada-4dbb-99be-c3f0cccd4eb4'	(b) (4)	
User entered '1'	System	07 Oct 2020 02:46:15
	System	07 Oct 2020 02:46:15
	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:46:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f65fb049-fada-4dbb-99be-c3f0cccd4eb4' User entered '06 Oct 2020 21:46'	System	07 Oct 2020 02:46:15
	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Oct 2020 18:30:59
User entered 'Day 29'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:33:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63481047-e1bd-4b8e-9ec5-7b4eb187951e'	System	07 Oct 2020 20:34:48
User entered 'Yes (Y)'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:34:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63481047-e1bd-4b8e-9ec5-7b4eb187951e'	System	07 Oct 2020 20:34:48
User entered '95.1'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:34:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63481047-e1bd-4b8e-9ec5-7b4eb187951e'	System	07 Oct 2020 20:34:48
User entered 'Yes (Y)'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:34:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63481047-e1bd-4b8e-9ec5-7b4eb187951e'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:30:02
User entered '1'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:28
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:34:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63481047-e1bd-4b8e-9ec5-7b4eb187951e'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:30:07
User entered '1'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:34:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63481047-e1bd-4b8e-9ec5-7b4eb187951e'	System	07 Oct 2020 20:34:48
User entered '07 Oct 2020 15:34'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	07 Oct 2020 02:46:15
User entered 'Day 30'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:52:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8f19d679-bd61-4ccc-a016-ac2a0edc14a0'	System	08 Oct 2020 18:53:19
User entered 'Yes (Y)'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:53:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8f19d679-bd61-4ccc-a016-ac2a0edc14a0'	System	08 Oct 2020 18:53:19
User entered '96.4'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:53:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8f19d679-bd61-4ccc-a016-ac2a0edc14a0'	System	08 Oct 2020 18:53:19
User entered 'Yes (Y)'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:53:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8f19d679-bd61-4ccc-a016-ac2a0edc14a0'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:30:20
User entered '1'	System	08 Oct 2020 18:53:19
	System	08 Oct 2020 18:53:19
	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:34
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:53:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8f19d679-bd61-4ccc-a016-ac2a0edc14a0'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:30:24
User entered '1'	System	08 Oct 2020 18:53:19
	System	08 Oct 2020 18:53:19
	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:53:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8f19d679-bd61-4ccc-a016-ac2a0edc14a0'	System	08 Oct 2020 18:53:19
User entered '08 Oct 2020 13:53'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	07 Oct 2020 20:34:48
User entered 'Day 31'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:41:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58aa3328-3c65-45b5-a053-7e125df315f9'	System	09 Oct 2020 17:42:11
User entered 'Yes (Y)'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:42:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58aa3328-3c65-45b5-a053-7e125df315f9'	System	09 Oct 2020 17:42:11
User entered '97.8'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:42:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58aa3328-3c65-45b5-a053-7e125df315f9'	System	09 Oct 2020 17:42:11
User entered 'Yes (Y)'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:42:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58aa3328-3c65-45b5-a053-7e125df315f9'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:30:31
User entered '1'	System	09 Oct 2020 17:42:11
	System	09 Oct 2020 17:42:11
	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:42:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58aa3328-3c65-45b5-a053-7e125df315f9'	System	09 Oct 2020 17:42:11
User entered '0'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:42:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58aa3328-3c65-45b5-a053-7e125df315f9'	System	09 Oct 2020 17:42:11
User entered '09 Oct 2020 12:42'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	08 Oct 2020 18:53:19
User entered 'Day 32'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:56:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9caeac7-5f74-41dd-8250-2f4c77f54aaf'	System	10 Oct 2020 21:57:12
User entered 'Yes (Y)'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:57:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9caeac7-5f74-41dd-8250-2f4c77f54aaf'	System	10 Oct 2020 21:57:12
User entered '95.7'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:57:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9caeac7-5f74-41dd-8250-2f4c77f54aaf'	System	10 Oct 2020 21:57:12
User entered 'Yes (Y)'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:57:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9caeac7-5f74-41dd-8250-2f4c77f54aaf'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:30:37
User entered '1'	System	10 Oct 2020 21:57:12
	System	10 Oct 2020 21:57:12
	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:43
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:30:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:57:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9caeac7-5f74-41dd-8250-2f4c77f54aaf'	(b) (4)	
User entered '1'	System	10 Oct 2020 21:57:12
	System	10 Oct 2020 21:57:12
	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:57:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd9caeac7-5f74-41dd-8250-2f4c77f54aaf'	System	10 Oct 2020 21:57:12
User entered '10 Oct 2020 16:57'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Oct 2020 17:42:11
User entered 'Day 33'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:33:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b28035fc-1b89-49ec-9058-14d7837a4268'	System	12 Oct 2020 12:34:26
User entered 'Yes (Y)'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:34:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b28035fc-1b89-49ec-9058-14d7837a4268'	System	12 Oct 2020 12:34:26
User entered '95.0'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:34:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b28035fc-1b89-49ec-9058-14d7837a4268'	System	12 Oct 2020 12:34:26
User entered 'Yes (Y)'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:34:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b28035fc-1b89-49ec-9058-14d7837a4268'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:30:50
User entered '1'	System	12 Oct 2020 12:34:26
	System	12 Oct 2020 12:34:26
	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:48
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:30:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:34:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b28035fc-1b89-49ec-9058-14d7837a4268'	(b) (4)	
User entered '1'	System	12 Oct 2020 12:34:26
	System	12 Oct 2020 12:34:26
	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:34:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b28035fc-1b89-49ec-9058-14d7837a4268'	System	12 Oct 2020 12:34:26
User entered '12 Oct 2020 07:34'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	10 Oct 2020 21:57:12
User entered 'Day 34'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96b17b29-a1c2-4456-a06e-2fa83c8f3f03'	System	12 Oct 2020 20:04:39
User entered 'Yes (Y)'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96b17b29-a1c2-4456-a06e-2fa83c8f3f03'	System	12 Oct 2020 20:04:39
User entered '97.0'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96b17b29-a1c2-4456-a06e-2fa83c8f3f03'	System	12 Oct 2020 20:04:39
User entered 'Yes (Y)'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96b17b29-a1c2-4456-a06e-2fa83c8f3f03'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:31:01
User entered '1'	System	12 Oct 2020 20:04:39
	System	12 Oct 2020 20:04:39
	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:54
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:31:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96b17b29-a1c2-4456-a06e-2fa83c8f3f03'	(b) (4)	
User entered '1'	System	12 Oct 2020 20:04:39
	System	12 Oct 2020 20:04:39
	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '96b17b29-a1c2-4456-a06e-2fa83c8f3f03'	System	12 Oct 2020 20:04:39
User entered '12 Oct 2020 15:04'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	12 Oct 2020 12:34:26
User entered 'Day 35'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2b045070-6945-4a77-923d-9d918762246a'	System	14 Oct 2020 01:12:45
User entered 'Yes (Y)'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2b045070-6945-4a77-923d-9d918762246a'	System	14 Oct 2020 01:12:45
User entered '96.5'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2b045070-6945-4a77-923d-9d918762246a'	System	14 Oct 2020 01:12:45
User entered 'Yes (Y)'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2b045070-6945-4a77-923d-9d918762246a'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:31:13
User entered '1'	System	14 Oct 2020 01:12:45
	System	14 Oct 2020 01:12:45
	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:55:59
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:31:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2b045070-6945-4a77-923d-9d918762246a'	System	14 Oct 2020 01:12:45
User entered '1'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2b045070-6945-4a77-923d-9d918762246a'	System	14 Oct 2020 01:12:45
User entered '13 Oct 2020 20:12'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(35)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	12 Oct 2020 20:04:39
User entered 'Day 36'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:51:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a27ca906-c698-4f96-9435-7d2d712d5269'	System	14 Oct 2020 17:52:08
User entered 'Yes (Y)'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:52:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a27ca906-c698-4f96-9435-7d2d712d5269'	System	14 Oct 2020 17:52:08
User entered '95.5'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:52:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a27ca906-c698-4f96-9435-7d2d712d5269'	System	14 Oct 2020 17:52:08
User entered 'Yes (Y)'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:52:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a27ca906-c698-4f96-9435-7d2d712d5269'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:31:26
User entered '1'	System	14 Oct 2020 17:52:08
	System	14 Oct 2020 17:52:08
	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:05
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:31:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:52:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a27ca906-c698-4f96-9435-7d2d712d5269'	(b) (4)	
User entered '1'	System	14 Oct 2020 17:52:08
	System	14 Oct 2020 17:52:08
	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:52:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a27ca906-c698-4f96-9435-7d2d712d5269'	System	14 Oct 2020 17:52:08
User entered '14 Oct 2020 12:52'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(36)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Oct 2020 01:12:45
User entered 'Day 37'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:10:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cca40e48-65ef-4d44-8536-668b27391d67'	System	15 Oct 2020 17:11:08
User entered 'Yes (Y)'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:10:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cca40e48-65ef-4d44-8536-668b27391d67'	System	15 Oct 2020 17:11:08
User entered '95.6'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:11:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cca40e48-65ef-4d44-8536-668b27391d67'	System	15 Oct 2020 17:11:08
User entered 'Yes (Y)'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:11:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cca40e48-65ef-4d44-8536-668b27391d67'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:31:38
User entered '1'	System	15 Oct 2020 17:11:08
	System	15 Oct 2020 17:11:08
	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:11
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:31:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:11:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cca40e48-65ef-4d44-8536-668b27391d67'	(b) (4)	
User entered '1'	System	15 Oct 2020 17:11:08
	System	15 Oct 2020 17:11:08
	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:11:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cca40e48-65ef-4d44-8536-668b27391d67'	System	15 Oct 2020 17:11:08
User entered '15 Oct 2020 12:11'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(37)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Oct 2020 17:52:08
User entered 'Day 38'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9bc53150-7c12-498d-9ddf-f60a3f1818b5'	System	17 Oct 2020 12:24:29
User entered 'Yes (Y)'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9bc53150-7c12-498d-9ddf-f60a3f1818b5'	System	17 Oct 2020 12:24:29
User entered '95.6'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9bc53150-7c12-498d-9ddf-f60a3f1818b5'	System	17 Oct 2020 12:24:29
User entered 'Yes (Y)'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9bc53150-7c12-498d-9ddf-f60a3f1818b5'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:31:50
User entered '1'	System	17 Oct 2020 12:24:29
	System	17 Oct 2020 12:24:29
	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:17
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:31:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9bc53150-7c12-498d-9ddf-f60a3f1818b5'	(b) (4)	
User entered '1'	System	17 Oct 2020 12:24:29
	System	17 Oct 2020 12:24:29
	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9bc53150-7c12-498d-9ddf-f60a3f1818b5'	System	17 Oct 2020 12:24:29
User entered '17 Oct 2020 07:24'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(38)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	15 Oct 2020 17:11:08
User entered 'Day 39'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:30:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9aa4f034-226c-446e-8df3-b650dac94b74'	System	18 Oct 2020 00:31:14
User entered 'Yes (Y)'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:31:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9aa4f034-226c-446e-8df3-b650dac94b74'	System	18 Oct 2020 00:31:14
User entered '98.0'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:31:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9aa4f034-226c-446e-8df3-b650dac94b74'	System	18 Oct 2020 00:31:14
User entered 'Yes (Y)'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:31:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9aa4f034-226c-446e-8df3-b650dac94b74'	System	18 Oct 2020 00:31:14
User entered '0'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:20
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:32:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:31:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9aa4f034-226c-446e-8df3-b650dac94b74'	(b) (4)	
User entered '1'	System	18 Oct 2020 00:31:14
	System	18 Oct 2020 00:31:14
	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:31:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9aa4f034-226c-446e-8df3-b650dac94b74'	System	18 Oct 2020 00:31:14
User entered '17 Oct 2020 19:31'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(39)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Oct 2020 12:24:29
User entered 'Day 40'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9314e55a-e0cc-410e-bf5e-e94de77d061a'	System	18 Oct 2020 22:09:26
User entered 'Yes (Y)'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9314e55a-e0cc-410e-bf5e-e94de77d061a'	System	18 Oct 2020 22:09:26
User entered '96.5'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9314e55a-e0cc-410e-bf5e-e94de77d061a'	System	18 Oct 2020 22:09:26
User entered 'Yes (Y)'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9314e55a-e0cc-410e-bf5e-e94de77d061a'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:32:07
User entered '1'	System	18 Oct 2020 22:09:26
	System	18 Oct 2020 22:09:26
	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:26
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:32:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9314e55a-e0cc-410e-bf5e-e94de77d061a'	(b) (4)	
User entered '1'	System	18 Oct 2020 22:09:26
	System	18 Oct 2020 22:09:26
	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9314e55a-e0cc-410e-bf5e-e94de77d061a'	System	18 Oct 2020 22:09:26
User entered '18 Oct 2020 17:09'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(40)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Oct 2020 00:31:14
User entered 'Day 41'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:13:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fc3aacea-2a66-4e8a-9a66-c91b0b9fc872'	System	19 Oct 2020 17:13:56
User entered 'Yes (Y)'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:13:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fc3aacea-2a66-4e8a-9a66-c91b0b9fc872'	System	19 Oct 2020 17:13:56
User entered '96.2'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:13:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fc3aacea-2a66-4e8a-9a66-c91b0b9fc872'	System	19 Oct 2020 17:13:56
User entered 'Yes (Y)'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:13:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fc3aacea-2a66-4e8a-9a66-c91b0b9fc872'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:32:20
User entered '1'	System	19 Oct 2020 17:13:56
	System	19 Oct 2020 17:13:56
	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:13:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fc3aacea-2a66-4e8a-9a66-c91b0b9fc872'	System	19 Oct 2020 17:13:56
User entered '0'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:13:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fc3aacea-2a66-4e8a-9a66-c91b0b9fc872'	System	19 Oct 2020 17:13:56
User entered '19 Oct 2020 12:13'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(41)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Oct 2020 22:09:26
User entered 'Day 42'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:36:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f12c9aa2-8d65-4671-a995-6057dd3d8727'	System	20 Oct 2020 21:37:09
User entered 'Yes (Y)'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:36:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f12c9aa2-8d65-4671-a995-6057dd3d8727'	System	20 Oct 2020 21:37:09
User entered '98.0'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:36:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f12c9aa2-8d65-4671-a995-6057dd3d8727'	System	20 Oct 2020 21:37:09
User entered 'Yes (Y)'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:37:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f12c9aa2-8d65-4671-a995-6057dd3d8727'	Tiffany Nemecek (b) (4) (b) (4)	21 Oct 2020 20:32:27
User entered '1'	System	20 Oct 2020 21:37:09
	System	20 Oct 2020 21:37:09
	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:35
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:32:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:37:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f12c9aa2-8d65-4671-a995-6057dd3d8727'	(b) (4)	
User entered '1'	System	20 Oct 2020 21:37:09
	System	20 Oct 2020 21:37:09
	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:37:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f12c9aa2-8d65-4671-a995-6057dd3d8727'	System	20 Oct 2020 21:37:09
User entered '20 Oct 2020 16:37'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(42)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	19 Oct 2020 17:13:56
User entered 'Day 43'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b591c59-8bd0-4e33-b192-ffd1041c91cb'	System	21 Oct 2020 17:10:17
User entered 'Yes (Y)'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b591c59-8bd0-4e33-b192-ffd1041c91cb'	System	21 Oct 2020 17:10:17
User entered '96.9'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b591c59-8bd0-4e33-b192-ffd1041c91cb'	System	21 Oct 2020 17:10:17
User entered 'Yes (Y)'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b591c59-8bd0-4e33-b192-ffd1041c91cb'	System	21 Oct 2020 17:10:17
User entered '0'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Corrected' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 14:56:40
User opened query 'Per the participant response, medication was taken to prevent 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).	Tiffany Nemecek (b) (4)	21 Oct 2020 20:32:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b591c59-8bd0-4e33-b192-ffd1041c91cb'	(b) (4)	
User entered '1'	System	21 Oct 2020 17:10:17
	System	21 Oct 2020 17:10:17
	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b591c59-8bd0-4e33-b192-ffd1041c91cb'	System	21 Oct 2020 17:10:17
User entered '21 Oct 2020 12:10'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(43)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Oct 2020 21:37:09
User entered 'Day 44'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f5e873a-5b5c-40f8-8bca-b9d45e2ec29f'	System	22 Oct 2020 21:04:40
User entered 'Yes (Y)'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f5e873a-5b5c-40f8-8bca-b9d45e2ec29f'	System	22 Oct 2020 21:04:40
User entered '95.6'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f5e873a-5b5c-40f8-8bca-b9d45e2ec29f'	System	22 Oct 2020 21:04:40
User entered 'Yes (Y)'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Oct 2020 21:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f5e873a-5b5c-40f8-8bca-b9d45e2ec29f'	System	22 Oct 2020 21:04:40
User entered '1'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:10
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Oct 2020 21:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f5e873a-5b5c-40f8-8bca-b9d45e2ec29f'	System	22 Oct 2020 21:04:40
User entered '1'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4f5e873a-5b5c-40f8-8bca-b9d45e2ec29f' User entered '22 Oct 2020 16:04'	System	22 Oct 2020 21:04:40
	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(44)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Oct 2020 17:10:17
User entered 'Day 45'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:53:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd11f06c3-def0-47c1-a6f5-02e12088cc77'	System	24 Oct 2020 01:54:00
User entered 'Yes (Y)'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:53:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd11f06c3-def0-47c1-a6f5-02e12088cc77'	System	24 Oct 2020 01:54:00
User entered '97.8'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:53:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd11f06c3-def0-47c1-a6f5-02e12088cc77'	System	24 Oct 2020 01:54:00
User entered 'Yes (Y)'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	24 Oct 2020 01:54:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:53:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd11f06c3-def0-47c1-a6f5-02e12088cc77'	System	24 Oct 2020 01:54:00
User entered '1'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:22
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	24 Oct 2020 01:54:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:53:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd11f06c3-def0-47c1-a6f5-02e12088cc77'	System	24 Oct 2020 01:54:00
User entered '1'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:54:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd11f06c3-def0-47c1-a6f5-02e12088cc77'	System	24 Oct 2020 01:54:00
User entered '23 Oct 2020 20:54'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(45)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Oct 2020 21:04:40
User entered 'Day 46'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:24:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a3cc706-f007-4cde-8f29-9e2c55e6d6ac'	System	25 Oct 2020 00:25:15
User entered 'Yes (Y)'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:24:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a3cc706-f007-4cde-8f29-9e2c55e6d6ac'	System	25 Oct 2020 00:25:15
User entered '97.9'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:25:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a3cc706-f007-4cde-8f29-9e2c55e6d6ac'	System	25 Oct 2020 00:25:15
User entered 'Yes (Y)'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Oct 2020 00:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:25:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a3cc706-f007-4cde-8f29-9e2c55e6d6ac'	System	25 Oct 2020 00:25:15
User entered '1'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:32
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Oct 2020 00:25:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:25:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a3cc706-f007-4cde-8f29-9e2c55e6d6ac'	System	25 Oct 2020 00:25:15
User entered '1'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:25:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a3cc706-f007-4cde-8f29-9e2c55e6d6ac'	System	25 Oct 2020 00:25:15
User entered '24 Oct 2020 19:25'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(46)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Oct 2020 01:54:00
User entered 'Day 47'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6642bf7b-10e7-4f2b-bf9a-6b26df7d37d7'	System	25 Oct 2020 17:18:33
User entered 'Yes (Y)'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6642bf7b-10e7-4f2b-bf9a-6b26df7d37d7'	System	25 Oct 2020 17:18:33
User entered '96.9'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6642bf7b-10e7-4f2b-bf9a-6b26df7d37d7'	System	25 Oct 2020 17:18:33
User entered 'Yes (Y)'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Oct 2020 17:18:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6642bf7b-10e7-4f2b-bf9a-6b26df7d37d7'	System	25 Oct 2020 17:18:33
User entered '1'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:44
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Oct 2020 17:18:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6642bf7b-10e7-4f2b-bf9a-6b26df7d37d7'	System	25 Oct 2020 17:18:33
User entered '1'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '6642bf7b-10e7-4f2b-bf9a-6b26df7d37d7'	System	25 Oct 2020 17:18:33
User entered '25 Oct 2020 12:18'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(47)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Oct 2020 00:25:15
User entered 'Day 48'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:39:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '685a6ee2-f4fc-457a-9679-b83aa48684a8'	System	26 Oct 2020 17:40:07
User entered 'Yes (Y)'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:39:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '685a6ee2-f4fc-457a-9679-b83aa48684a8'	System	26 Oct 2020 17:40:07
User entered '95.4'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:39:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '685a6ee2-f4fc-457a-9679-b83aa48684a8'	System	26 Oct 2020 17:40:07
User entered 'Yes (Y)'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 18:42:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:39:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '685a6ee2-f4fc-457a-9679-b83aa48684a8'	System	26 Oct 2020 17:40:07
User entered '1'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:27:54
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Oct 2020 17:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:39:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '685a6ee2-f4fc-457a-9679-b83aa48684a8'	System	26 Oct 2020 17:40:07
User entered '1'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:40:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '685a6ee2-f4fc-457a-9679-b83aa48684a8'	System	26 Oct 2020 17:40:07
User entered '26 Oct 2020 12:40'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(48)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Oct 2020 17:18:33
User entered 'Day 49'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ed9f74-627d-4cad-8c6d-d9b7b6e526d2'	System	28 Oct 2020 06:05:17
User entered 'Yes (Y)'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ed9f74-627d-4cad-8c6d-d9b7b6e526d2'	System	28 Oct 2020 06:05:17
User entered '95.6'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ed9f74-627d-4cad-8c6d-d9b7b6e526d2'	System	28 Oct 2020 06:05:17
User entered 'Yes (Y)'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Oct 2020 06:05:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ed9f74-627d-4cad-8c6d-d9b7b6e526d2'	System	28 Oct 2020 06:05:17
User entered '1'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:05
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Oct 2020 06:05:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ed9f74-627d-4cad-8c6d-d9b7b6e526d2'	System	28 Oct 2020 06:05:17
User entered '1'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79ed9f74-627d-4cad-8c6d-d9b7b6e526d2'	System	28 Oct 2020 06:05:17
User entered '28 Oct 2020 01:05'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(49)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	26 Oct 2020 17:40:07
User entered 'Day 50'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '542aacc0-fb7e-4e81-8455-8972a086ed07'	System	28 Oct 2020 23:38:32
User entered 'Yes (Y)'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '542aacc0-fb7e-4e81-8455-8972a086ed07'	System	28 Oct 2020 23:38:32
User entered '96.3'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '542aaec0-fb7e-4e81-8455-8972a086ed07'	System	28 Oct 2020 23:38:32
User entered 'Yes (Y)'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Oct 2020 23:38:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '542aacc0-fb7e-4e81-8455-8972a086ed07'	System	28 Oct 2020 23:38:32
User entered '1'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:15
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Oct 2020 23:38:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '542aaec0-fb7e-4e81-8455-8972a086ed07'	System	28 Oct 2020 23:38:32
User entered '1'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '542aacc0-fb7e-4e81-8455-8972a086ed07'	System	28 Oct 2020 23:38:32
User entered '28 Oct 2020 18:38'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(50)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Oct 2020 06:05:17
User entered 'Day 51'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:30:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '013f7dc9-75cf-474b-a197-d7dd6d7c088c'	System	29 Oct 2020 22:31:09
User entered 'Yes (Y)'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:30:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '013f7dc9-75cf-474b-a197-d7dd6d7c088c'	System	29 Oct 2020 22:31:09
User entered '96.8'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:31:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '013f7dc9-75cf-474b-a197-d7dd6d7c088c'	System	29 Oct 2020 22:31:09
User entered 'Yes (Y)'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Oct 2020 22:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:31:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '013f7dc9-75cf-474b-a197-d7dd6d7c088c'	System	29 Oct 2020 22:31:09
User entered '1'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:28
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Oct 2020 22:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:31:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '013f7dc9-75cf-474b-a197-d7dd6d7c088c'	System	29 Oct 2020 22:31:09
User entered '1'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:31:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '013f7dc9-75cf-474b-a197-d7dd6d7c088c'	System	29 Oct 2020 22:31:09
User entered '29 Oct 2020 17:31'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(51)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Oct 2020 23:38:32
User entered 'Day 52'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:16:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1ca4415e-d001-444d-aac1-f1a4a2d30f42'	System	30 Oct 2020 20:16:54
User entered 'Yes (Y)'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:16:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1ca4415e-d001-444d-aac1-f1a4a2d30f42'	System	30 Oct 2020 20:16:54
User entered '96.2'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:16:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1ca4415e-d001-444d-aac1-f1a4a2d30f42'	System	30 Oct 2020 20:16:54
User entered 'Yes (Y)'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Oct 2020 20:16:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:16:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1ca4415e-d001-444d-aac1-f1a4a2d30f42'	System	30 Oct 2020 20:16:54
User entered '1'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:37
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Oct 2020 20:16:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:16:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1ca4415e-d001-444d-aac1-f1a4a2d30f42'	System	30 Oct 2020 20:16:54
User entered '1'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:16:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1ca4415e-d001-444d-aac1-f1a4a2d30f42'	System	30 Oct 2020 20:16:54
User entered '30 Oct 2020 15:16'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(52)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Oct 2020 22:31:09
User entered 'Day 53'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fa31a85d-c8d1-46e9-b376-837d1f6d0878'	System	01 Nov 2020 01:42:57
User entered 'Yes (Y)'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fa31a85d-c8d1-46e9-b376-837d1f6d0878'	System	01 Nov 2020 01:42:57
User entered '96.7'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fa31a85d-c8d1-46e9-b376-837d1f6d0878'	System	01 Nov 2020 01:42:57
User entered 'Yes (Y)'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Nov 2020 01:42:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fa31a85d-c8d1-46e9-b376-837d1f6d0878'	System	01 Nov 2020 01:42:57
User entered '1'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:49
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Nov 2020 01:42:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fa31a85d-c8d1-46e9-b376-837d1f6d0878'	System	01 Nov 2020 01:42:57
User entered '1'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fa31a85d-c8d1-46e9-b376-837d1f6d0878'	System	01 Nov 2020 01:42:57
User entered '31 Oct 2020 20:42'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(53)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	30 Oct 2020 20:16:54
User entered 'Day 54'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81b35b01-ef68-443e-b575-0b837a419ed5'	System	01 Nov 2020 18:24:28
User entered 'Yes (Y)'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81b35b01-ef68-443e-b575-0b837a419ed5'	System	01 Nov 2020 18:24:28
User entered '96.6'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81b35b01-ef68-443e-b575-0b837a419ed5'	System	01 Nov 2020 18:24:28
User entered 'Yes (Y)'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Nov 2020 18:24:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81b35b01-ef68-443e-b575-0b837a419ed5'	System	01 Nov 2020 18:24:28
User entered '1'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:28:59
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Nov 2020 18:24:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81b35b01-ef68-443e-b575-0b837a419ed5'	System	01 Nov 2020 18:24:28
User entered '1'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81b35b01-ef68-443e-b575-0b837a419ed5'	System	01 Nov 2020 18:24:28
User entered '01 Nov 2020 12:24'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(54)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	01 Nov 2020 01:42:57
User entered 'Day 55'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:12:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd18b1160-7541-4446-800b-3baecb25355e'	System	02 Nov 2020 18:12:54
User entered 'Yes (Y)'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:12:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd18b1160-7541-4446-800b-3baecb25355e'	System	02 Nov 2020 18:12:54
User entered '95.7'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:12:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd18b1160-7541-4446-800b-3baecb25355e'	System	02 Nov 2020 18:12:54
User entered 'Yes (Y)'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:29:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Nov 2020 18:12:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:12:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd18b1160-7541-4446-800b-3baecb25355e'	System	02 Nov 2020 18:12:54
User entered '1'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:12:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd18b1160-7541-4446-800b-3baecb25355e'	System	02 Nov 2020 18:12:54
User entered '0'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:12:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd18b1160-7541-4446-800b-3baecb25355e'	System	02 Nov 2020 18:12:54
User entered '02 Nov 2020 12:12'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(55)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	01 Nov 2020 18:24:28
User entered 'Day 56'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:43:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8f3d774-0afd-4f56-b69f-a15e6fad2cf8'	System	03 Nov 2020 21:44:05
User entered 'Yes (Y)'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:43:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8f3d774-0afd-4f56-b69f-a15e6fad2cf8'	System	03 Nov 2020 21:44:05
User entered '96.2'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:43:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8f3d774-0afd-4f56-b69f-a15e6fad2cf8'	System	03 Nov 2020 21:44:05
User entered 'Yes (Y)'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:29:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Nov 2020 21:44:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:43:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8f3d774-0afd-4f56-b69f-a15e6fad2cf8'	System	03 Nov 2020 21:44:05
User entered '1'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:29:22
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Nov 2020 21:44:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:43:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8f3d774-0afd-4f56-b69f-a15e6fad2cf8'	System	03 Nov 2020 21:44:05
User entered '1'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:44:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b8f3d774-0afd-4f56-b69f-a15e6fad2cf8'	System	03 Nov 2020 21:44:05
User entered '03 Nov 2020 15:44'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(56)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Nov 2020 18:12:54
User entered 'Day 57'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:46:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81c86ae6-5ab1-4cca-a9e2-a78e878411d1'	System	04 Nov 2020 18:46:59
User entered 'Yes (Y)'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:46:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81c86ae6-5ab1-4cca-a9e2-a78e878411d1'	System	04 Nov 2020 18:46:59
User entered '97.8'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:46:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81c86ae6-5ab1-4cca-a9e2-a78e878411d1'	System	04 Nov 2020 18:46:59
User entered 'Yes (Y)'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:31:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 18:44:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:46:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81c86ae6-5ab1-4cca-a9e2-a78e878411d1'	System	04 Nov 2020 18:46:59
User entered '1'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:31:34
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Nov 2020 18:46:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:46:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81c86ae6-5ab1-4cca-a9e2-a78e878411d1'	System	04 Nov 2020 18:46:59
User entered '1'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:46:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '81c86ae6-5ab1-4cca-a9e2-a78e878411d1'	System	04 Nov 2020 18:46:59
User entered '04 Nov 2020 12:46'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(57)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	03 Nov 2020 21:44:05
User entered 'Day 58'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7531082-f66e-44cb-a9f3-fe63d4531996'	System	05 Nov 2020 22:47:29
User entered 'Yes (Y)'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7531082-f66e-44cb-a9f3-fe63d4531996'	System	05 Nov 2020 22:47:29
User entered '96.7'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7531082-f66e-44cb-a9f3-fe63d4531996'	System	05 Nov 2020 22:47:29
User entered 'Yes (Y)'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:31:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	05 Nov 2020 22:47:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7531082-f66e-44cb-a9f3-fe63d4531996'	System	05 Nov 2020 22:47:29
User entered '1'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:31:45
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	05 Nov 2020 22:47:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7531082-f66e-44cb-a9f3-fe63d4531996'	System	05 Nov 2020 22:47:29
User entered '1'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7531082-f66e-44cb-a9f3-fe63d4531996'	System	05 Nov 2020 22:47:29
User entered '05 Nov 2020 16:47'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(58)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	04 Nov 2020 18:46:59
User entered 'Day 59'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:44:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5bfda708-94c9-4821-9bc5-3c4911b33ec4'	System	06 Nov 2020 21:45:11
User entered 'Yes (Y)'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:44:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5bfda708-94c9-4821-9bc5-3c4911b33ec4'	System	06 Nov 2020 21:45:11
User entered '96.1'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:45:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5bfda708-94c9-4821-9bc5-3c4911b33ec4'	System	06 Nov 2020 21:45:11
User entered 'Yes (Y)'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:31:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Nov 2020 21:45:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:45:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5bfda708-94c9-4821-9bc5-3c4911b33ec4'	System	06 Nov 2020 21:45:11
User entered '1'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:45:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5bfda708-94c9-4821-9bc5-3c4911b33ec4'	System	06 Nov 2020 21:45:11
User entered '0'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:45:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5bfda708-94c9-4821-9bc5-3c4911b33ec4'	System	06 Nov 2020 21:45:11
User entered '06 Nov 2020 15:45'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(59)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Nov 2020 22:47:29
User entered 'Day 60'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:35:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '261661e8-16f8-48a0-9c4c-36d76fbdf6a6'	System	08 Nov 2020 01:35:49
User entered 'Yes (Y)'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:35:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '261661e8-16f8-48a0-9c4c-36d76fbdfea6'	System	08 Nov 2020 01:35:49
User entered '97.8'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:35:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '261661e8-16f8-48a0-9c4c-36d76fbdf6a6'	System	08 Nov 2020 01:35:49
User entered 'Yes (Y)'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:32:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Nov 2020 01:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:35:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '261661e8-16f8-48a0-9c4c-36d76bfdfea6'	System	08 Nov 2020 01:35:49
User entered '1'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:32:05
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Nov 2020 01:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:35:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '261661e8-16f8-48a0-9c4c-36d76fdbfea6'	System	08 Nov 2020 01:35:49
User entered '1'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:35:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '261661e8-16f8-48a0-9c4c-36d76fbdf6a6'	System	08 Nov 2020 01:35:49
User entered '07 Nov 2020 19:35'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(60)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	06 Nov 2020 21:45:11
User entered 'Day 61'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7b0b371-370c-4159-ab25-e68cbf1cdf41'	System	09 Nov 2020 01:13:47
User entered 'Yes (Y)'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7b0b371-370c-4159-ab25-e68cbf1cdf41'	System	09 Nov 2020 01:13:47
User entered '97.6'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7b0b371-370c-4159-ab25-e68cbf1cdf41'	System	09 Nov 2020 01:13:47
User entered 'Yes (Y)'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:32:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Nov 2020 01:13:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7b0b371-370c-4159-ab25-e68cbf1cdf41'	System	09 Nov 2020 01:13:47
User entered '1'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:32:18
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Nov 2020 01:13:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7b0b371-370c-4159-ab25-e68cbf1cdf41'	System	09 Nov 2020 01:13:47
User entered '1'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7b0b371-370c-4159-ab25-e68cbf1cdf41'	System	09 Nov 2020 01:13:47
User entered '08 Nov 2020 19:13'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(61)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	08 Nov 2020 01:35:49
User entered 'Day 62'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db56e3f0-7d17-41b9-9802-304248889377'	System	09 Nov 2020 19:49:27
User entered 'Yes (Y)'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db56e3f0-7d17-41b9-9802-304248889377'	System	09 Nov 2020 19:49:27
User entered '97.6'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db56e3f0-7d17-41b9-9802-304248889377'	System	09 Nov 2020 19:49:27
User entered 'Yes (Y)'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:32:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 18:45:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db56e3f0-7d17-41b9-9802-304248889377'	System	09 Nov 2020 19:49:27
User entered '1'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject contacted. Marked medication taken for pain for being a bilateral leg amputee. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:32:28
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Nov 2020 19:49:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db56e3f0-7d17-41b9-9802-304248889377'	System	09 Nov 2020 19:49:27
User entered '1'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db56e3f0-7d17-41b9-9802-304248889377'	System	09 Nov 2020 19:49:27
User entered '09 Nov 2020 13:49'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Nov 2020 12:00'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(62)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Nov 2020 11:59'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Nov 2020 01:13:47
User entered 'Day 63'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe3f0f26-9c67-4631-9bc9-2115aceeedee'	System	10 Nov 2020 23:58:39
User entered 'Yes (Y)'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe3f0f26-9c67-4631-9bc9-2115aceeedee'	System	10 Nov 2020 23:58:39
User entered '96.2'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe3f0f26-9c67-4631-9bc9-2115aceeedee'	System	10 Nov 2020 23:58:39
User entered 'Yes (Y)'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'subject is a bilateral leg amputee and pain medications taken daily. Not for COVID like illness' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 08:55:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Nov 2020 23:58:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe3f0f26-9c67-4631-9bc9-2115aceeedee'	System	10 Nov 2020 23:58:39
User entered '1'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'subject is a bilateral leg amputee and pain medications taken daily. Not for COVID like illness' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 08:55:15
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Nov 2020 23:58:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe3f0f26-9c67-4631-9bc9-2115aceeedee'	System	10 Nov 2020 23:58:39
User entered '1'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe3f0f26-9c67-4631-9bc9-2115aceeedee'	System	10 Nov 2020 23:58:39
User entered '10 Nov 2020 17:58'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(63)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Nov 2020 19:49:27
User entered 'Day 64'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f14dcd40-eef1-4b49-afe4-418209e4e060'	System	11 Nov 2020 21:57:33
User entered 'Yes (Y)'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f14dcd40-eef1-4b49-afe4-418209e4e060' User entered '96.7'	System	11 Nov 2020 21:57:33
	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f14dcd40-eef1-4b49-afe4-418209e4e060'	System	11 Nov 2020 21:57:33
User entered 'Yes (Y)'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'subject bilateral leg amputee. Pain meds taken for that ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 08:55:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Nov 2020 21:57:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f14dcd40-eef1-4b49-afe4-418209e4e060'	System	11 Nov 2020 21:57:33
User entered '1'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'subject bilateral leg amputee. Pain meds taken for that ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 08:56:01
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Nov 2020 21:57:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f14dcd40-eef1-4b49-afe4-418209e4e060'	System	11 Nov 2020 21:57:33
User entered '1'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f14dcd40-eef1-4b49-afe4-418209e4e060'	System	11 Nov 2020 21:57:33
User entered '11 Nov 2020 15:57'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(64)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	10 Nov 2020 23:58:39
User entered 'Day 65'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:17:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58c858e1-a2ce-40eb-9468-c332e30db52e'	System	12 Nov 2020 22:18:12
User entered 'Yes (Y)'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:17:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58c858e1-a2ce-40eb-9468-c332e30db52e'	System	12 Nov 2020 22:18:12
User entered '96.8'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:18:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58c858e1-a2ce-40eb-9468-c332e30db52e'	System	12 Nov 2020 22:18:12
User entered 'Yes (Y)'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'subject is bilateral leg amputee. pain med taken for that' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 08:56:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Nov 2020 22:18:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:18:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58c858e1-a2ce-40eb-9468-c332e30db52e'	System	12 Nov 2020 22:18:12
User entered '1'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'subject is bilateral leg amputee. pain med taken for that' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 08:56:05
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Nov 2020 22:18:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:18:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58c858e1-a2ce-40eb-9468-c332e30db52e'	System	12 Nov 2020 22:18:12
User entered '1'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:18:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '58c858e1-a2ce-40eb-9468-c332e30db52e'	System	12 Nov 2020 22:18:12
User entered '12 Nov 2020 16:18'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(65)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Nov 2020 21:57:33
User entered 'Day 66'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '91c186ba-9b43-4c98-9455-cc48ab415c13'	System	14 Nov 2020 02:11:33
User entered 'Yes (Y)'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '91c186ba-9b43-4c98-9455-cc48ab415c13'	System	14 Nov 2020 02:11:33
User entered '96.6'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '91c186ba-9b43-4c98-9455-cc48ab415c13'	System	14 Nov 2020 02:11:33
User entered 'Yes (Y)'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'subject bilateral leg amputee. pain medication taken for that not other illness' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:44:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:31:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '91c186ba-9b43-4c98-9455-cc48ab415c13'	System	14 Nov 2020 02:11:33
User entered '1'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'subject bilateral leg amputee. pain medication taken for that not other illness' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:44:09
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Nov 2020 02:11:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '91c186ba-9b43-4c98-9455-cc48ab415c13'	System	14 Nov 2020 02:11:33
User entered '1'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '91c186ba-9b43-4c98-9455-cc48ab415c13'	System	14 Nov 2020 02:11:33
User entered '13 Nov 2020 20:11'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(66)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	12 Nov 2020 22:18:12
User entered 'Day 67'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:01:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd71d1765-6ea3-4b51-a1b6-96f414ee0eeb'	System	14 Nov 2020 20:02:06
User entered 'Yes (Y)'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:01:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd71d1765-6ea3-4b51-a1b6-96f414ee0eeb' User entered '97.5'	System	14 Nov 2020 20:02:06
	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:01:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd71d1765-6ea3-4b51-a1b6-96f414ee0eeb'	System	14 Nov 2020 20:02:06
User entered 'Yes (Y)'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'subject bilateral leg amputee. pain medication taken for that not other illness' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:44:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:31:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:01:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd71d1765-6ea3-4b51-a1b6-96f414ee0eeb'	System	14 Nov 2020 20:02:06
User entered '1'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:01:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd71d1765-6ea3-4b51-a1b6-96f414ee0eeb'	System	14 Nov 2020 20:02:06
User entered '0'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:02:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd71d1765-6ea3-4b51-a1b6-96f414ee0eeb'	System	14 Nov 2020 20:02:06
User entered '14 Nov 2020 14:02'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(67)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Nov 2020 02:11:33
User entered 'Day 68'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:09:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a075fdd0-c046-4ac5-8d10-0145dfc30138'	System	15 Nov 2020 18:10:08
User entered 'Yes (Y)'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:09:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a075fdd0-c046-4ac5-8d10-0145dfc30138'	System	15 Nov 2020 18:10:08
User entered '97.8'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:09:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a075fdd0-c046-4ac5-8d10-0145dfc30138'	System	15 Nov 2020 18:10:08
User entered 'Yes (Y)'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'subject bilateral leg amputee. pain medication taken for that not other illness' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:44:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:31:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:10:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a075fdd0-c046-4ac5-8d10-0145dfc30138'	System	15 Nov 2020 18:10:08
User entered '1'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'subject bilateral leg amputee. pain medication taken for that not other illness' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:45:02
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	17 Nov 2020 16:31:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:10:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a075fdd0-c046-4ac5-8d10-0145dfc30138'	System	15 Nov 2020 18:10:08
User entered '1'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:10:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a075fdd0-c046-4ac5-8d10-0145dfc30138'	System	15 Nov 2020 18:10:08
User entered '15 Nov 2020 12:10'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(68)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Nov 2020 20:02:06
User entered 'Day 69'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:42:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a1dbd819-0b65-4972-a44e-c0859d2013f8'	System	16 Nov 2020 18:42:58
User entered 'Yes (Y)'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:42:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a1dbd819-0b65-4972-a44e-c0859d2013f8' User entered '98.1'	System	16 Nov 2020 18:42:58
	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:42:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a1dbd819-0b65-4972-a44e-c0859d2013f8'	System	16 Nov 2020 18:42:58
User entered 'Yes (Y)'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'subject bilateral leg amputee. pain medication taken for that not other illness' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:45:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:42:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a1dbd819-0b65-4972-a44e-c0859d2013f8'	System	16 Nov 2020 18:42:58
User entered '1'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'subject bilateral leg amputee. pain medication taken for that not other illness' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:45:31
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Nov 2020 18:42:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:42:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a1dbd819-0b65-4972-a44e-c0859d2013f8'	System	16 Nov 2020 18:42:58
User entered '1'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:42:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a1dbd819-0b65-4972-a44e-c0859d2013f8'	System	16 Nov 2020 18:42:58
User entered '16 Nov 2020 12:42'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Nov 2020 12:00'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(69)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Nov 2020 11:59'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	15 Nov 2020 18:10:08
User entered 'Day 70'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97ad0c0b-8f1a-4c1c-ba92-0bb660d1770e'	System	17 Nov 2020 19:21:37
User entered 'Yes (Y)'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97ad0c0b-8f1a-4c1c-ba92-0bb660d1770e'	System	17 Nov 2020 19:21:37
User entered '95.8'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97ad0c0b-8f1a-4c1c-ba92-0bb660d1770e'	System	17 Nov 2020 19:21:37
User entered 'Yes (Y)'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'Subject is a bilateral leg amputee and this medication is for that not illness symptoms' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:45:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 20:17:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97ad0c0b-8f1a-4c1c-ba92-0bb660d1770e'	System	17 Nov 2020 19:21:37
User entered '1'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Subject is a bilateral leg amputee and this medication is for that not illness symptoms' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:45:56
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	17 Nov 2020 20:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97ad0c0b-8f1a-4c1c-ba92-0bb660d1770e'	System	17 Nov 2020 19:21:37
User entered '1'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97ad0c0b-8f1a-4c1c-ba92-0bb660d1770e'	System	17 Nov 2020 19:21:37
User entered '17 Nov 2020 13:21'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(70)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	16 Nov 2020 18:42:58
User entered 'Day 71'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:45:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9b0e7c17-42cb-4ca7-a1ac-2955785fe017'	System	18 Nov 2020 19:46:06
User entered 'Yes (Y)'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:45:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9b0e7c17-42cb-4ca7-a1ac-2955785fe017'	System	18 Nov 2020 19:46:06
User entered '97.2'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:45:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9b0e7c17-42cb-4ca7-a1ac-2955785fe017'	System	18 Nov 2020 19:46:06
User entered 'Yes (Y)'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:10:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:46:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9b0e7c17-42cb-4ca7-a1ac-2955785fe017'	System	18 Nov 2020 19:46:06
User entered '1'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:24
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	23 Nov 2020 19:10:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:46:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9b0e7c17-42cb-4ca7-a1ac-2955785fe017'	System	18 Nov 2020 19:46:06
User entered '1'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:46:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9b0e7c17-42cb-4ca7-a1ac-2955785fe017'	System	18 Nov 2020 19:46:06
User entered '18 Nov 2020 13:46'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(71)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Nov 2020 19:21:37
User entered 'Day 72'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12b76a59-c80e-43df-8b22-f6c1284f0fd3'	System	20 Nov 2020 12:53:54
User entered 'Yes (Y)'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12b76a59-c80e-43df-8b22-f6c1284f0fd3'	System	20 Nov 2020 12:53:54
User entered '97.1'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12b76a59-c80e-43df-8b22-f6c1284f0fd3'	System	20 Nov 2020 12:53:54
User entered 'Yes (Y)'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12b76a59-c80e-43df-8b22-f6c1284f0fd3'	System	20 Nov 2020 12:53:54
User entered '0'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:31
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	23 Nov 2020 19:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12b76a59-c80e-43df-8b22-f6c1284f0fd3'	System	20 Nov 2020 12:53:54
User entered '1'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12b76a59-c80e-43df-8b22-f6c1284f0fd3'	System	20 Nov 2020 12:53:54
User entered '20 Nov 2020 06:53'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Nov 2020 12:00'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(72)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Nov 2020 11:59'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Nov 2020 19:46:06
User entered 'Day 73'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:15:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '73b94501-22a8-4901-b7c2-b410d6e16b48'	System	21 Nov 2020 04:16:07
User entered 'Yes (Y)'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:15:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '73b94501-22a8-4901-b7c2-b410d6e16b48'	System	21 Nov 2020 04:16:07
User entered '97.2'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:15:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '73b94501-22a8-4901-b7c2-b410d6e16b48'	System	21 Nov 2020 04:16:07
User entered 'Yes (Y)'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:10:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:16:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '73b94501-22a8-4901-b7c2-b410d6e16b48'	System	21 Nov 2020 04:16:07
User entered '1'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:43
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	23 Nov 2020 19:10:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:16:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '73b94501-22a8-4901-b7c2-b410d6e16b48'	System	21 Nov 2020 04:16:07
User entered '1'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:16:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '73b94501-22a8-4901-b7c2-b410d6e16b48'	System	21 Nov 2020 04:16:07
User entered '20 Nov 2020 22:16'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(73)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Nov 2020 12:53:54
User entered 'Day 74'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63a3ada6-415f-43c2-bf15-5ac2a6e3a20a'	System	22 Nov 2020 03:30:51
User entered 'Yes (Y)'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63a3ada6-415f-43c2-bf15-5ac2a6e3a20a'	System	22 Nov 2020 03:30:51
User entered '96.0'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63a3ada6-415f-43c2-bf15-5ac2a6e3a20a'	System	22 Nov 2020 03:30:51
User entered 'Yes (Y)'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:11:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63a3ada6-415f-43c2-bf15-5ac2a6e3a20a'	System	22 Nov 2020 03:30:51
User entered '1'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:52
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	23 Nov 2020 19:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63a3ada6-415f-43c2-bf15-5ac2a6e3a20a'	System	22 Nov 2020 03:30:51
User entered '1'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63a3ada6-415f-43c2-bf15-5ac2a6e3a20a'	System	22 Nov 2020 03:30:51
User entered '21 Nov 2020 21:30'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(74)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Nov 2020 04:16:07
User entered 'Day 75'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97e88a48-bc35-492a-a6ce-8d79b37bbe9b'	System	22 Nov 2020 22:51:22
User entered 'Yes (Y)'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97e88a48-bc35-492a-a6ce-8d79b37bbe9b'	System	22 Nov 2020 22:51:22
User entered '97.7'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97e88a48-bc35-492a-a6ce-8d79b37bbe9b'	System	22 Nov 2020 22:51:22
User entered 'Yes (Y)'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:36:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:11:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97e88a48-bc35-492a-a6ce-8d79b37bbe9b'	System	22 Nov 2020 22:51:22
User entered '1'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:37:02
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	23 Nov 2020 19:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97e88a48-bc35-492a-a6ce-8d79b37bbe9b'	System	22 Nov 2020 22:51:22
User entered '1'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '97e88a48-bc35-492a-a6ce-8d79b37bbe9b'	System	22 Nov 2020 22:51:22
User entered '22 Nov 2020 16:51'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(75)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Nov 2020 03:30:51
User entered 'Day 76'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:13:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e2b3ba8-18f2-4c85-9e2d-5eb374bcc590'	System	23 Nov 2020 18:14:02
User entered 'Yes (Y)'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:13:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e2b3ba8-18f2-4c85-9e2d-5eb374bcc590'	System	23 Nov 2020 18:14:02
User entered '98.0'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:13:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e2b3ba8-18f2-4c85-9e2d-5eb374bcc590'	System	23 Nov 2020 18:14:02
User entered 'Yes (Y)'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:37:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:13:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e2b3ba8-18f2-4c85-9e2d-5eb374bcc590'	System	23 Nov 2020 18:14:02
User entered '1'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'No new medication taken. Patient inadvertently took medication for bilateral leg amputations that is captured on medical history. ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 09:37:12
User opened query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	23 Nov 2020 19:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:13:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e2b3ba8-18f2-4c85-9e2d-5eb374bcc590'	System	23 Nov 2020 18:14:02
User entered '1'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:14:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e2b3ba8-18f2-4c85-9e2d-5eb374bcc590'	System	23 Nov 2020 18:14:02
User entered '23 Nov 2020 12:14'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(76)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Nov 2020 22:51:22
User entered 'Day 77'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:45:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fff5193a-9d7a-4812-ba02-6c1bc81842c6'	System	24 Nov 2020 22:45:55
User entered 'Yes (Y)'	System	24 Nov 2020 22:45:55

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:45:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fff5193a-9d7a-4812-ba02-6c1bc81842c6'	System	24 Nov 2020 22:45:55
User entered '97.3'	System	24 Nov 2020 22:45:55

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:45:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fff5193a-9d7a-4812-ba02-6c1bc81842c6'	System	24 Nov 2020 22:45:55
User entered 'Yes (Y)'	System	24 Nov 2020 22:45:55

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
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 'contacted patient about medication taken for pain. patient states no new medication was taken. patient is a bilateral leg amputee so he takes medication daily for the pain.' (Site from System).	(b) (4), (b) (6)	27 Nov 2020 06:10:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 15:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:45:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fff5193a-9d7a-4812-ba02-6c1bc81842c6'	System	24 Nov 2020 22:45:55
User entered '1'	System	24 Nov 2020 22:45:55

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:45:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fff5193a-9d7a-4812-ba02-6c1bc81842c6'	System	24 Nov 2020 22:45:55
User entered '0'	System	24 Nov 2020 22:45:55

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:45:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fff5193a-9d7a-4812-ba02-6c1bc81842c6'	System	24 Nov 2020 22:45:55
User entered '24 Nov 2020 16:45'	System	24 Nov 2020 22:45:55

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Nov 2020 12:00'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(77)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Nov 2020 11:59'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	23 Nov 2020 18:14:02
User entered 'Day 78'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-25T16:44:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '376cbc70-851b-46cf-b8b3-15eaa33e52c2'	System	25 Nov 2020 22:44:26
User entered 'Yes (Y)'	System	25 Nov 2020 22:44:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-25T16:44:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '376cbc70-851b-46cf-b8b3-15eaa33e52c2'	System	25 Nov 2020 22:44:26
User entered '97.8'	System	25 Nov 2020 22:44:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-25T16:44:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '376cbc70-851b-46cf-b8b3-15eaa33e52c2'	System	25 Nov 2020 22:44:26
User entered 'No (N)'	System	25 Nov 2020 22:44:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-25T16:44:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '376cbc70-851b-46cf-b8b3-15eaa33e52c2'	System	25 Nov 2020 22:44:26
User entered '25 Nov 2020 16:44'	System	25 Nov 2020 22:44:26

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(78)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd2d4be6a-2a56-4a06-b16a-1871d3708c95'	System	09 Sep 2020 16:38:50
User entered 'None (1)'	System	09 Sep 2020 16:38:50

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd2d4be6a-2a56-4a06-b16a-1871d3708c95'	System	09 Sep 2020 16:38:50
User entered 'No (N)'	System	09 Sep 2020 16:38:50

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd2d4be6a-2a56-4a06-b16a-1871d3708c95'	System	09 Sep 2020 16:38:50
User entered 'No (N)'	System	09 Sep 2020 16:38:50

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd2d4be6a-2a56-4a06-b16a-1871d3708c95'	System	09 Sep 2020 16:38:50
User entered 'None (1)'	System	09 Sep 2020 16:38:50

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd2d4be6a-2a56-4a06-b16a-1871d3708c95'	System	09 Sep 2020 16:38:50
User entered '09 Sep 2020 11:38'	System	09 Sep 2020 16:38:50

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 11:28'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 13:58'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f19051c-8232-4751-9473-d073bf58be26'	System	09 Sep 2020 19:57:48
User entered 'None (1)'	System	09 Sep 2020 19:57:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f19051c-8232-4751-9473-d073bf58be26'	System	09 Sep 2020 19:57:48
User entered 'No (N)'	System	09 Sep 2020 19:57:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f19051c-8232-4751-9473-d073bf58be26'	System	09 Sep 2020 19:57:48
User entered 'No (N)'	System	09 Sep 2020 19:57:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f19051c-8232-4751-9473-d073bf58be26'	System	09 Sep 2020 19:57:48
User entered 'None (1)'	System	09 Sep 2020 19:57:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1f19051c-8232-4751-9473-d073bf58be26'	System	09 Sep 2020 19:57:48
User entered '09 Sep 2020 14:57'	System	09 Sep 2020 19:57:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 14:53'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 2'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0baf038-0a1c-40a4-b8dd-e240854c99fb'	System	10 Sep 2020 17:11:19
User entered 'None (1)'	System	10 Sep 2020 17:11:19

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0bafe038-0a1c-40a4-b8dd-e240854c99fb'	System	10 Sep 2020 17:11:19
User entered 'No (N)'	System	10 Sep 2020 17:11:19

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0baf038-0a1c-40a4-b8dd-e240854c99fb'	System	10 Sep 2020 17:11:19
User entered 'No (N)'	System	10 Sep 2020 17:11:19

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0bafe038-0a1c-40a4-b8dd-e240854c99fb'	System	10 Sep 2020 17:11:19
User entered 'None (1)'	System	10 Sep 2020 17:11:19

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0baf038-0a1c-40a4-b8dd-e240854c99fb'	System	10 Sep 2020 17:11:19
User entered '10 Sep 2020 12:11'	System	10 Sep 2020 17:11:19

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 3'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c84c8534-b09a-4ba6-98d6-394ab3355738'	System	11 Sep 2020 20:01:16
User entered 'None (1)'	System	11 Sep 2020 20:01:16

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c84c8534-b09a-4ba6-98d6-394ab3355738'	System	11 Sep 2020 20:01:16
User entered 'No (N)'	System	11 Sep 2020 20:01:16

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c84c8534-b09a-4ba6-98d6-394ab3355738'	System	11 Sep 2020 20:01:16
User entered 'No (N)'	System	11 Sep 2020 20:01:16

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c84c8534-b09a-4ba6-98d6-394ab3355738'	System	11 Sep 2020 20:01:16
User entered 'None (1)'	System	11 Sep 2020 20:01:16

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c84c8534-b09a-4ba6-98d6-394ab3355738'	System	11 Sep 2020 20:01:16
User entered '11 Sep 2020 15:01'	System	11 Sep 2020 20:01:16

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 4'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:03:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07b942b5-3938-4209-91d1-69a06c562a8f'	System	12 Sep 2020 22:04:09
User entered 'None (1)'	System	12 Sep 2020 22:04:09

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07b942b5-3938-4209-91d1-69a06c562a8f'	System	12 Sep 2020 22:04:09
User entered 'No (N)'	System	12 Sep 2020 22:04:09

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07b942b5-3938-4209-91d1-69a06c562a8f'	System	12 Sep 2020 22:04:09
User entered 'No (N)'	System	12 Sep 2020 22:04:09

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07b942b5-3938-4209-91d1-69a06c562a8f'	System	12 Sep 2020 22:04:09
User entered 'None (1)'	System	12 Sep 2020 22:04:09

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '07b942b5-3938-4209-91d1-69a06c562a8f'	System	12 Sep 2020 22:04:09
User entered '12 Sep 2020 17:04'	System	12 Sep 2020 22:04:09

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 5'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3a86df79-408e-4ff6-9a7e-fa178f21176e'	System	13 Sep 2020 20:04:35
User entered 'None (1)'	System	13 Sep 2020 20:04:35

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3a86df79-408e-4ff6-9a7e-fa178f21176e'	System	13 Sep 2020 20:04:35
User entered 'No (N)'	System	13 Sep 2020 20:04:35

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3a86df79-408e-4ff6-9a7e-fa178f21176e'	System	13 Sep 2020 20:04:35
User entered 'No (N)'	System	13 Sep 2020 20:04:35

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3a86df79-408e-4ff6-9a7e-fa178f21176e'	System	13 Sep 2020 20:04:35
User entered 'None (1)'	System	13 Sep 2020 20:04:35

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:38', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3a86df79-408e-4ff6-9a7e-fa178f21176e'	System	13 Sep 2020 20:04:35
User entered '13 Sep 2020 15:04'	System	13 Sep 2020 20:04:35

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 6'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2aa98c4a-5a1c-4150-8809-bc58566d8d30'	System	14 Sep 2020 21:18:48
User entered 'None (1)'	System	14 Sep 2020 21:18:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2aa98c4a-5a1c-4150-8809-bc58566d8d30'	System	14 Sep 2020 21:18:48
User entered 'No (N)'	System	14 Sep 2020 21:18:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Is there any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2aa98c4a-5a1c-4150-8809-bc58566d8d30'	System	14 Sep 2020 21:18:48
User entered 'No (N)'	System	14 Sep 2020 21:18:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2aa98c4a-5a1c-4150-8809-bc58566d8d30'	System	14 Sep 2020 21:18:48
User entered 'None (1)'	System	14 Sep 2020 21:18:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2aa98c4a-5a1c-4150-8809-bc58566d8d30'	System	14 Sep 2020 21:18:48
User entered '14 Sep 2020 16:18'	System	14 Sep 2020 21:18:48

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 7'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe0a96ca-ea2f-4cde-bca1-9f02348da139'	System	15 Sep 2020 18:12:43
User entered 'None (1)'	System	15 Sep 2020 18:12:43

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe0a96ca-ea2f-4cde-bca1-9f02348da139'	System	15 Sep 2020 18:12:43
User entered 'No (N)'	System	15 Sep 2020 18:12:43

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe0a96ca-ea2f-4cde-bca1-9f02348da139'	System	15 Sep 2020 18:12:43
User entered 'No (N)'	System	15 Sep 2020 18:12:43

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe0a96ca-ea2f-4cde-bca1-9f02348da139'	System	15 Sep 2020 18:12:43
User entered 'None (1)'	System	15 Sep 2020 18:12:43

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe0a96ca-ea2f-4cde-bca1-9f02348da139'	System	15 Sep 2020 18:12:43
User entered '15 Sep 2020 13:12'	System	15 Sep 2020 18:12:43

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:38:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered 'None (0)'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:39:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered 'None (0)'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:39:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered 'None (0)'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:39:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered 'None (0)'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:39:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered 'None (0)'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:39:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered 'None (0)'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:39:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered 'No (N)'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T11:39:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3fa33eac-f888-4912-8f6d-f4687c6747af'	System	09 Sep 2020 16:39:25
User entered '09 Sep 2020 11:39'	System	09 Sep 2020 16:39:25

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 11:28'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 13:58'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered 'None (0)'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered 'None (0)'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:57:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered 'None (0)'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:58:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered 'None (0)'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:58:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered 'None (0)'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:58:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered 'None (0)'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:58:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered 'No (N)'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-09T14:58:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '75fbee3b-8569-493a-921f-ca5d1d6be79b'	System	10 Sep 2020 17:10:30
User entered '09 Sep 2020 14:58'	System	10 Sep 2020 17:10:30

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Sep 2020 14:53'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 2'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered 'None (0)'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered 'None (0)'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered 'None (0)'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered 'None (0)'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered 'None (0)'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered 'None (0)'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered 'No (N)'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-10T12:11:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ca7c5d8-032c-45e0-8c8e-dd0291719ae7'	System	10 Sep 2020 17:11:43
User entered '10 Sep 2020 12:11'	System	10 Sep 2020 17:11:43

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 3'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered 'None (0)'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered 'None (0)'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered 'None (0)'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered 'None (0)'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered 'None (0)'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered 'None (0)'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered 'No (N)'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-11T15:01:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9e79e298-94ac-40fb-b204-fc22214541e2'	System	11 Sep 2020 20:01:38
User entered '11 Sep 2020 15:01'	System	11 Sep 2020 20:01:38

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 4'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered 'None (0)'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered 'None (0)'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered 'None (0)'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered 'None (0)'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered 'None (0)'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered 'None (0)'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered 'No (N)'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-12T17:04:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56248134-4909-4822-9af9-567d044bef0d'	System	12 Sep 2020 22:04:32
User entered '12 Sep 2020 17:04'	System	12 Sep 2020 22:04:32

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 5'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered 'None (0)'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered 'None (0)'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered 'None (0)'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered 'None (0)'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered 'None (0)'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered 'None (0)'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered 'No (N)'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-13T15:04:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5f527332-2b13-4aef-a48a-86d953d64c94'	System	13 Sep 2020 20:04:55
User entered '13 Sep 2020 15:04'	System	13 Sep 2020 20:04:55

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 6'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered 'None (0)'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered 'None (0)'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered 'None (0)'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered 'None (0)'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered 'None (0)'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered 'None (0)'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered 'No (N)'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-14T16:18:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '29bd6393-ae3a-40de-94a9-61772271714f'	System	14 Sep 2020 21:19:03
User entered '14 Sep 2020 16:18'	System	14 Sep 2020 21:19:03

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Sep 2020 16:36:15
User entered 'Day 7'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered 'None (0)'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered 'None (0)'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered 'None (0)'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered 'None (0)'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered 'None (0)'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered 'None (0)'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:12:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered 'No (N)'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-15T13:13:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '612f1faf-58c8-46c1-bc35-6cf43667a865'	System	15 Sep 2020 18:13:06
User entered '15 Sep 2020 13:13'	System	15 Sep 2020 18:13:06

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:36:15

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Sep 2020 21:18:21
User entered 'Day 8'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b477b693-350b-49d8-acdb-7749ebbb26e1'	System	17 Sep 2020 00:13:03
User entered 'No (N)'	System	17 Sep 2020 00:13:03

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-16T19:12:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b477b693-350b-49d8-acdb-7749ebbb26e1'	System	17 Sep 2020 00:13:03
User entered '16 Sep 2020 19:12'	System	17 Sep 2020 00:13:03

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:18:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	15 Sep 2020 18:12:24
User entered 'Day 9'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:44:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '807604bb-0d39-4b03-a295-27c663acee6d'	System	17 Sep 2020 21:44:06
User entered 'No (N)'	System	17 Sep 2020 21:44:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-17T16:44:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '807604bb-0d39-4b03-a295-27c663acee6d'	System	17 Sep 2020 21:44:06
User entered '17 Sep 2020 16:44'	System	17 Sep 2020 21:44:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 18:12:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Sep 2020 00:12:56
User entered 'Day 10'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0f37e14a-67d7-46be-9c73-b8abf7b7d846'	System	18 Sep 2020 20:31:54
User entered 'No (N)'	System	18 Sep 2020 20:31:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-18T15:31:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0f37e14a-67d7-46be-9c73-b8abf7b7d846'	System	18 Sep 2020 20:31:54
User entered '18 Sep 2020 15:31'	System	18 Sep 2020 20:31:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:12:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Sep 2020 21:43:58
User entered 'Day 11'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '39476ce7-ce68-4d6e-9682-179a38a7c200'	System	19 Sep 2020 20:41:06
User entered 'No (N)'	System	19 Sep 2020 20:41:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-19T15:41:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '39476ce7-ce68-4d6e-9682-179a38a7c200'	System	19 Sep 2020 20:41:06
User entered '19 Sep 2020 15:41'	System	19 Sep 2020 20:41:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 21:43:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Sep 2020 20:31:44
User entered 'Day 12'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:15:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b56817fb-c909-451a-a382-f24cfe051902'	System	20 Sep 2020 21:15:07
User entered 'No (N)'	System	20 Sep 2020 21:15:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-20T16:15:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b56817fb-c909-451a-a382-f24cfe051902'	System	20 Sep 2020 21:15:07
User entered '20 Sep 2020 16:15'	System	20 Sep 2020 21:15:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 20:31:44

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	19 Sep 2020 20:41:24
User entered 'Day 13'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2c7d987b-b751-4f78-a15c-696024e84b10'	System	21 Sep 2020 20:02:42
User entered 'No (N)'	System	21 Sep 2020 20:02:42

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-21T15:02:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2c7d987b-b751-4f78-a15c-696024e84b10'	System	21 Sep 2020 20:02:42
User entered '21 Sep 2020 15:02'	System	21 Sep 2020 20:02:42

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 20:41:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Sep 2020 21:14:58
User entered 'Day 14'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '36757f3d-98a9-4c6f-bfaf-0be1db32d448'	System	22 Sep 2020 20:14:26
User entered 'No (N)'	System	22 Sep 2020 20:14:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-22T15:14:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '36757f3d-98a9-4c6f-bfaf-0be1db32d448'	System	22 Sep 2020 20:14:26
User entered '22 Sep 2020 15:14'	System	22 Sep 2020 20:14:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 21:14:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Sep 2020 20:02:36
User entered 'Day 15'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:24:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a9fce8c7-f4a3-471d-a3c3-6a0c1a07eccc'	System	24 Sep 2020 10:24:58
User entered 'No (N)'	System	24 Sep 2020 10:24:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T05:24:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a9fce8c7-f4a3-471d-a3c3-6a0c1a07eccc'	System	24 Sep 2020 10:24:58
User entered '24 Sep 2020 05:24'	System	24 Sep 2020 10:24:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 20:02:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Sep 2020 20:14:19
User entered 'Day 16'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db345b95-a1de-4b3a-9d5a-89ce30e75279'	System	24 Sep 2020 17:53:34
User entered 'No (N)'	System	24 Sep 2020 17:53:34

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-24T12:53:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'db345b95-a1de-4b3a-9d5a-89ce30e75279'	System	24 Sep 2020 17:53:34
User entered '24 Sep 2020 12:53'	System	24 Sep 2020 17:53:34

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:14:19

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Sep 2020 10:24:50
User entered 'Day 17'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:09:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b053595-c251-46fd-8023-11037ac60398'	System	25 Sep 2020 22:09:13
User entered 'No (N)'	System	25 Sep 2020 22:09:13

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-25T17:09:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0b053595-c251-46fd-8023-11037ac60398'	System	25 Sep 2020 22:09:13
User entered '25 Sep 2020 17:09'	System	25 Sep 2020 22:09:13

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 10:24:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Sep 2020 17:53:26
User entered 'Day 18'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '874643f9-690a-4f90-9071-17cbc9503419'	System	26 Sep 2020 17:40:56
User entered 'No (N)'	System	26 Sep 2020 17:40:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-26T12:40:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '874643f9-690a-4f90-9071-17cbc9503419'	System	26 Sep 2020 17:40:56
User entered '26 Sep 2020 12:40'	System	26 Sep 2020 17:40:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:53:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Sep 2020 22:09:07
User entered 'Day 19'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e938b52e-f456-49bf-83dc-25db10b8505e'	System	28 Sep 2020 00:46:00
User entered 'No (N)'	System	28 Sep 2020 00:46:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-27T19:45:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e938b52e-f456-49bf-83dc-25db10b8505e'	System	28 Sep 2020 00:46:00
User entered '27 Sep 2020 19:45'	System	28 Sep 2020 00:46:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 22:09:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	26 Sep 2020 17:40:46
User entered 'Day 20'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ded2ae55-0040-4ef9-a850-72723aa47c6e'	System	29 Sep 2020 11:03:41
User entered 'No (N)'	System	29 Sep 2020 11:03:41

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T06:03:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ded2ae55-0040-4ef9-a850-72723aa47c6e'	System	29 Sep 2020 11:03:41
User entered '29 Sep 2020 06:03'	System	29 Sep 2020 11:03:41

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:40:46

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Sep 2020 00:45:53
User entered 'Day 21'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9984583b-04d2-4c58-8589-98902e7291e0'	System	29 Sep 2020 18:41:03
User entered 'No (N)'	System	29 Sep 2020 18:41:03

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-29T13:40:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9984583b-04d2-4c58-8589-98902e7291e0'	System	29 Sep 2020 18:41:03
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 18:41:03

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 00:45:53

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Sep 2020 11:03:37
User entered 'Day 22'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '35ba0957-50f6-4df3-a00e-834adae0b825'	System	30 Sep 2020 17:32:18
User entered 'No (N)'	System	30 Sep 2020 17:32:18

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-09-30T12:31:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '35ba0957-50f6-4df3-a00e-834adae0b825'	System	30 Sep 2020 17:32:18
User entered '30 Sep 2020 12:31'	System	30 Sep 2020 17:32:18

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:03:37

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Sep 2020 18:40:50
User entered 'Day 23'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:05:59', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2ca9091b-eb0d-4b8c-a32f-29b3b87dd442'	System	02 Oct 2020 01:06:05
User entered 'No (N)'	System	02 Oct 2020 01:06:05

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-01T20:06:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2ca9091b-eb0d-4b8c-a32f-29b3b87dd442'	System	02 Oct 2020 01:06:05
User entered '01 Oct 2020 20:06'	System	02 Oct 2020 01:06:05

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:40:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	30 Sep 2020 17:32:12
User entered 'Day 24'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:37:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5534d017-e3e9-47df-8505-d1736e6fc2b8'	System	02 Oct 2020 23:37:09
User entered 'No (N)'	System	02 Oct 2020 23:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-02T18:37:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5534d017-e3e9-47df-8505-d1736e6fc2b8'	System	02 Oct 2020 23:37:09
User entered '02 Oct 2020 18:37'	System	02 Oct 2020 23:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:32:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Oct 2020 01:05:54
User entered 'Day 25'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '712bd03e-632d-4eed-bc43-4600e003ed5c'	System	03 Oct 2020 20:52:45
User entered 'No (N)'	System	03 Oct 2020 20:52:45

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-03T15:52:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '712bd03e-632d-4eed-bc43-4600e003ed5c'	System	03 Oct 2020 20:52:45
User entered '03 Oct 2020 15:52'	System	03 Oct 2020 20:52:45

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 01:05:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Oct 2020 23:37:00
User entered 'Day 26'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '24284213-9996-42a9-a5f8-a67742e69198'	System	04 Oct 2020 17:16:00
User entered 'No (N)'	System	04 Oct 2020 17:16:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-04T12:15:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '24284213-9996-42a9-a5f8-a67742e69198'	System	04 Oct 2020 17:16:00
User entered '04 Oct 2020 12:15'	System	04 Oct 2020 17:16:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 23:37:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	03 Oct 2020 20:52:40
User entered 'Day 27'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:31:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '99c4b84c-6543-4ced-8a4b-455b28fe0c8d'	System	05 Oct 2020 18:31:07
User entered 'No (N)'	System	05 Oct 2020 18:31:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-05T13:31:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '99c4b84c-6543-4ced-8a4b-455b28fe0c8d' User entered '05 Oct 2020 13:31'	System	05 Oct 2020 18:31:07
	System	05 Oct 2020 18:31:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 20:52:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	04 Oct 2020 17:15:54
User entered 'Day 28'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:46:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79fdae9f-ca44-4aa2-b3f7-db7fc7fdee53'	System	07 Oct 2020 02:46:25
User entered 'No (N)'	System	07 Oct 2020 02:46:25

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-06T21:46:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '79fdae9f-ca44-4aa2-b3f7-db7fc7fdee53'	System	07 Oct 2020 02:46:25
User entered '06 Oct 2020 21:46'	System	07 Oct 2020 02:46:25

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 17:15:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Oct 2020 18:30:59
User entered 'Day 29'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:34:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '51cbc6dd-5e8e-4b85-b5c0-003ddc3be082'	System	07 Oct 2020 20:34:53
User entered 'No (N)'	System	07 Oct 2020 20:34:53

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-07T15:34:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '51cbc6dd-5e8e-4b85-b5c0-003ddc3be082'	System	07 Oct 2020 20:34:53
User entered '07 Oct 2020 15:34'	System	07 Oct 2020 20:34:53

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 18:30:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	07 Oct 2020 02:46:15
User entered 'Day 30'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:53:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f99eab02-f0b6-4d1a-88bd-3ffd9d79fd7d'	System	08 Oct 2020 18:53:24
User entered 'No (N)'	System	08 Oct 2020 18:53:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-08T13:53:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'f99eab02-f0b6-4d1a-88bd-3ffd9d79fd7d' User entered '08 Oct 2020 13:53'	System	08 Oct 2020 18:53:24
	System	08 Oct 2020 18:53:24

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:46:15

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	07 Oct 2020 20:34:48
User entered 'Day 31'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:42:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7b76f7a1-2eb2-4851-bb45-00f019138b44'	System	09 Oct 2020 17:42:20
User entered 'No (N)'	System	09 Oct 2020 17:42:20

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-09T12:42:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7b76f7a1-2eb2-4851-bb45-00f019138b44'	System	09 Oct 2020 17:42:20
User entered '09 Oct 2020 12:42'	System	09 Oct 2020 17:42:20

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:34:48

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	08 Oct 2020 18:53:19
User entered 'Day 32'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:57:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'eef6cb85-dbdd-45a9-b2ab-34d00c462b9c'	System	10 Oct 2020 21:57:23
User entered 'No (N)'	System	10 Oct 2020 21:57:23

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-10T16:57:21', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'eef6cb85-dbdd-45a9-b2ab-34d00c462b9c'	System	10 Oct 2020 21:57:23
User entered '10 Oct 2020 16:57'	System	10 Oct 2020 21:57:23

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:53:19

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Oct 2020 17:42:11
User entered 'Day 33'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:34:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b569bf71-9f2f-4348-aefb-a33ae99ac7a1'	System	12 Oct 2020 12:34:31
User entered 'No (N)'	System	12 Oct 2020 12:34:31

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T07:34:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b569bf71-9f2f-4348-aefb-a33ae99ac7a1' User entered '12 Oct 2020 07:34'	System	12 Oct 2020 12:34:31
	System	12 Oct 2020 12:34:31

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:42:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	10 Oct 2020 21:57:12
User entered 'Day 34'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '95c063fd-5aa7-449c-a528-35d8f9ecc68c'	System	12 Oct 2020 20:04:44
User entered 'No (N)'	System	12 Oct 2020 20:04:44

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-12T15:04:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '95c063fd-5aa7-449c-a528-35d8f9ecc68c'	System	12 Oct 2020 20:04:44
User entered '12 Oct 2020 15:04'	System	12 Oct 2020 20:04:44

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 21:57:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	12 Oct 2020 12:34:26
User entered 'Day 35'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ba3f4fa-1f0f-4653-99c2-df42fc5f305b'	System	14 Oct 2020 01:12:50
User entered 'No (N)'	System	14 Oct 2020 01:12:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-13T20:12:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '3ba3f4fa-1f0f-4653-99c2-df42fc5f305b'	System	14 Oct 2020 01:12:50
User entered '13 Oct 2020 20:12'	System	14 Oct 2020 01:12:50

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 12:34:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	12 Oct 2020 20:04:39
User entered 'Day 36'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:52:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a5fc656-d06f-4fed-97ad-c5867f3fa4a5'	System	14 Oct 2020 17:52:16
User entered 'No (N)'	System	14 Oct 2020 17:52:16

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-14T12:52:17', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8a5fc656-d06f-4fed-97ad-c5867f3fa4a5'	System	14 Oct 2020 17:52:16
User entered '14 Oct 2020 12:52'	System	14 Oct 2020 17:52:16

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:04:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Oct 2020 01:12:45
User entered 'Day 37'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:11:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd0fa296e-a617-4226-bd7d-b4a43ee974e1'	System	15 Oct 2020 17:11:12
User entered 'No (N)'	System	15 Oct 2020 17:11:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-15T12:11:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd0fa296e-a617-4226-bd7d-b4a43ee974e1'	System	15 Oct 2020 17:11:12
User entered '15 Oct 2020 12:11'	System	15 Oct 2020 17:11:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 01:12:45

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Oct 2020 17:52:08
User entered 'Day 38'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b620ddba-a51e-43a6-810e-d8d6166518c5'	System	17 Oct 2020 12:24:36
User entered 'No (N)'	System	17 Oct 2020 12:24:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T07:24:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b620ddba-a51e-43a6-810e-d8d6166518c5'	System	17 Oct 2020 12:24:36
User entered '17 Oct 2020 07:24'	System	17 Oct 2020 12:24:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:52:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	15 Oct 2020 17:11:08
User entered 'Day 39'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:31:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63d2d932-bcec-4610-985a-49272c18b75c'	System	18 Oct 2020 00:31:21
User entered 'No (N)'	System	18 Oct 2020 00:31:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-17T19:31:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '63d2d932-bcec-4610-985a-49272c18b75c'	System	18 Oct 2020 00:31:21
User entered '17 Oct 2020 19:31'	System	18 Oct 2020 00:31:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:11:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Oct 2020 12:24:29
User entered 'Day 40'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c915d055-3aea-41e8-9547-e1dacabf72ba'	System	18 Oct 2020 22:09:36
User entered 'No (N)'	System	18 Oct 2020 22:09:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T17:09:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c915d055-3aea-41e8-9547-e1dacabf72ba' User entered '18 Oct 2020 17:09'	System	18 Oct 2020 22:09:36
	System	18 Oct 2020 22:09:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 12:24:29

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Oct 2020 00:31:14
User entered 'Day 41'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:14:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e9b1cf57-10e4-4a17-b91f-5b23895110e5'	System	19 Oct 2020 17:14:08
User entered 'No (N)'	System	19 Oct 2020 17:14:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-19T12:14:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'e9b1cf57-10e4-4a17-b91f-5b23895110e5'	System	19 Oct 2020 17:14:08
User entered '19 Oct 2020 12:14'	System	19 Oct 2020 17:14:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 00:31:14

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Oct 2020 22:09:26
User entered 'Day 42'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:37:11', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8440ec6-3c49-4188-b307-43b6334d6c56'	System	20 Oct 2020 21:37:12
User entered 'No (N)'	System	20 Oct 2020 21:37:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-20T16:37:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd8440ec6-3c49-4188-b307-43b6334d6c56'	System	20 Oct 2020 21:37:12
User entered '20 Oct 2020 16:37'	System	20 Oct 2020 21:37:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 22:09:26

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	19 Oct 2020 17:13:56
User entered 'Day 43'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4b446db-9d09-437c-92b5-69cd49f9c2d1'	System	21 Oct 2020 17:10:21
User entered 'No (N)'	System	21 Oct 2020 17:10:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-21T12:10:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a4b446db-9d09-437c-92b5-69cd49f9c2d1'	System	21 Oct 2020 17:10:21
User entered '21 Oct 2020 12:10'	System	21 Oct 2020 17:10:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:13:56

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Oct 2020 21:37:09
User entered 'Day 44'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '95f0b21e-3326-458b-a40e-6523906f9987'	System	22 Oct 2020 21:04:43
User entered 'No (N)'	System	22 Oct 2020 21:04:43

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-22T16:04:44', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '95f0b21e-3326-458b-a40e-6523906f9987'	System	22 Oct 2020 21:04:43
User entered '22 Oct 2020 16:04'	System	22 Oct 2020 21:04:43

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 21:37:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Oct 2020 17:10:17
User entered 'Day 45'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:54:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c3d23327-4871-40b6-ade7-5277a7bd1e90'	System	25 Oct 2020 00:24:47
User entered 'No (N)'	System	25 Oct 2020 00:24:47

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-23T20:54:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c3d23327-4871-40b6-ade7-5277a7bd1e90' User entered '23 Oct 2020 20:54'	System	25 Oct 2020 00:24:47
	System	25 Oct 2020 00:24:47

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 17:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Oct 2020 21:04:40
User entered 'Day 46'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:25:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd56c3e8b-b998-44c3-82cd-4e83b32b96ec'	System	25 Oct 2020 00:25:21
User entered 'No (N)'	System	25 Oct 2020 00:25:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-24T19:25:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd56c3e8b-b998-44c3-82cd-4e83b32b96ec'	System	25 Oct 2020 00:25:21
User entered '24 Oct 2020 19:25'	System	25 Oct 2020 00:25:21

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 21:04:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	24 Oct 2020 01:54:00
User entered 'Day 47'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2d60e3e5-436c-4161-b2b9-b70281db63d4'	System	25 Oct 2020 17:18:38
User entered 'No (N)'	System	25 Oct 2020 17:18:38

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T12:18:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2d60e3e5-436c-4161-b2b9-b70281db63d4'	System	25 Oct 2020 17:18:38
User entered '25 Oct 2020 12:18'	System	25 Oct 2020 17:18:38

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:54:00

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Oct 2020 00:25:15
User entered 'Day 48'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:40:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e643e5a-b9ac-4761-b94a-8f006981b2ac'	System	26 Oct 2020 17:40:12
User entered 'No (N)'	System	26 Oct 2020 17:40:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-26T12:40:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '0e643e5a-b9ac-4761-b94a-8f006981b2ac'	System	26 Oct 2020 17:40:12
User entered '26 Oct 2020 12:40'	System	26 Oct 2020 17:40:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 00:25:15

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	25 Oct 2020 17:18:33
User entered 'Day 49'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a00545f2-330d-4307-8576-e5b2bc12ac82'	System	28 Oct 2020 06:05:23
User entered 'No (N)'	System	28 Oct 2020 06:05:23

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T01:05:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a00545f2-330d-4307-8576-e5b2bc12ac82'	System	28 Oct 2020 06:05:23
User entered '28 Oct 2020 01:05'	System	28 Oct 2020 06:05:23

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 17:18:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	26 Oct 2020 17:40:07
User entered 'Day 50'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56f7dbfc-e433-460e-8be4-113290e88282'	System	28 Oct 2020 23:38:36
User entered 'No (N)'	System	28 Oct 2020 23:38:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-28T18:38:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '56f7dbfc-e433-460e-8be4-113290e88282'	System	28 Oct 2020 23:38:36
User entered '28 Oct 2020 18:38'	System	28 Oct 2020 23:38:36

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:40:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Oct 2020 06:05:17
User entered 'Day 51'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:31:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5c190d87-608b-4b35-8eb1-d79e0b7ff6ab'	System	29 Oct 2020 22:31:17
User entered 'No (N)'	System	29 Oct 2020 22:31:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-29T17:31:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5c190d87-608b-4b35-8eb1-d79e0b7ff6ab' User entered '29 Oct 2020 17:31'	System	29 Oct 2020 22:31:17
	System	29 Oct 2020 22:31:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 06:05:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	28 Oct 2020 23:38:32
User entered 'Day 52'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:16:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b02def3f-bd16-4808-8fd2-cbc72e02daa9'	System	30 Oct 2020 20:17:02
User entered 'No (N)'	System	30 Oct 2020 20:17:02

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-30T15:17:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b02def3f-bd16-4808-8fd2-cbc72e02daa9'	System	30 Oct 2020 20:17:02
User entered '30 Oct 2020 15:17'	System	30 Oct 2020 20:17:02

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 23:38:32

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	29 Oct 2020 22:31:09
User entered 'Day 53'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:55', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a3993bd9-604a-467d-b0ee-f25681c5035c'	System	01 Nov 2020 01:43:03
User entered 'No (N)'	System	01 Nov 2020 01:43:03

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-31T20:42:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a3993bd9-604a-467d-b0ee-f25681c5035c'	System	01 Nov 2020 01:43:03
User entered '31 Oct 2020 20:42'	System	01 Nov 2020 01:43:03

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 22:31:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	30 Oct 2020 20:16:54
User entered 'Day 54'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7fcb1a31-57a2-492c-b872-c1b2183920d3'	System	01 Nov 2020 18:24:35
User entered 'No (N)'	System	01 Nov 2020 18:24:35

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-01T12:24:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7fcb1a31-57a2-492c-b872-c1b2183920d3'	System	01 Nov 2020 18:24:35
User entered '01 Nov 2020 12:24'	System	01 Nov 2020 18:24:35

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 20:16:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	01 Nov 2020 01:42:57
User entered 'Day 55'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:12:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1c063508-789b-4cf9-88be-a16f814aa2bd'	System	02 Nov 2020 18:13:02
User entered 'No (N)'	System	02 Nov 2020 18:13:02

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-02T12:13:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '1c063508-789b-4cf9-88be-a16f814aa2bd'	System	02 Nov 2020 18:13:02
User entered '02 Nov 2020 12:13'	System	02 Nov 2020 18:13:02

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 01:42:57

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	01 Nov 2020 18:24:28
User entered 'Day 56'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:44:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4ffd7013-8c86-4c05-83c2-d6eafaa3a814'	System	03 Nov 2020 21:44:16
User entered 'No (N)'	System	03 Nov 2020 21:44:16

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-03T15:44:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4ffd7013-8c86-4c05-83c2-d6eafaa3a814'	System	03 Nov 2020 21:44:16
User entered '03 Nov 2020 15:44'	System	03 Nov 2020 21:44:16

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 18:24:28

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	02 Nov 2020 18:12:54
User entered 'Day 57'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:47:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4153b114-59bf-43b1-b20a-8dc62513b536'	System	04 Nov 2020 18:47:08
User entered 'No (N)'	System	04 Nov 2020 18:47:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-04T12:47:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4153b114-59bf-43b1-b20a-8dc62513b536'	System	04 Nov 2020 18:47:08
User entered '04 Nov 2020 12:47'	System	04 Nov 2020 18:47:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 18:12:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	03 Nov 2020 21:44:05
User entered 'Day 58'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:31', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '24987077-5e86-469a-a9e7-b6ee08f98fea'	System	05 Nov 2020 22:47:35
User entered 'No (N)'	System	05 Nov 2020 22:47:35

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-05T16:47:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '24987077-5e86-469a-a9e7-b6ee08f98fea'	System	05 Nov 2020 22:47:35
User entered '05 Nov 2020 16:47'	System	05 Nov 2020 22:47:35

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 21:44:05

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	04 Nov 2020 18:46:59
User entered 'Day 59'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:45:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12fb8827-01cf-4e5f-85b5-309008c9315b'	System	06 Nov 2020 21:45:22
User entered 'No (N)'	System	06 Nov 2020 21:45:22

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-06T15:45:22', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '12fb8827-01cf-4e5f-85b5-309008c9315b'	System	06 Nov 2020 21:45:22
User entered '06 Nov 2020 15:45'	System	06 Nov 2020 21:45:22

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:46:59

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	05 Nov 2020 22:47:29
User entered 'Day 60'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:35:58', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '00cb9e96-ab21-4670-a5e4-39f91a3f719d'	System	08 Nov 2020 01:36:04
User entered 'No (N)'	System	08 Nov 2020 01:36:04

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-07T19:36:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '00cb9e96-ab21-4670-a5e4-39f91a3f719d'	System	08 Nov 2020 01:36:04
User entered '07 Nov 2020 19:36'	System	08 Nov 2020 01:36:04

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 22:47:29

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	06 Nov 2020 21:45:11
User entered 'Day 61'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:49', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'dff78d59-7c3c-47ce-ab08-e0701c4398c4'	System	09 Nov 2020 01:13:52
User entered 'No (N)'	System	09 Nov 2020 01:13:52

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T19:13:51', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'dff78d59-7c3c-47ce-ab08-e0701c4398c4'	System	09 Nov 2020 01:13:52
User entered '08 Nov 2020 19:13'	System	09 Nov 2020 01:13:52

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 21:45:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	08 Nov 2020 01:35:49
User entered 'Day 62'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5158c748-8a6c-42bb-a738-cea6a0b71dc6'	System	09 Nov 2020 19:49:32
User entered 'No (N)'	System	09 Nov 2020 19:49:32

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-09T13:49:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '5158c748-8a6c-42bb-a738-cea6a0b71dc6' User entered '09 Nov 2020 13:49'	System	09 Nov 2020 19:49:32
	System	09 Nov 2020 19:49:32

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '09 Nov 2020 12:00'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Nov 2020 11:59'	System	08 Nov 2020 01:35:49

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Nov 2020 01:13:47
User entered 'Day 63'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7563f445-09fc-43ca-a51d-d9e7731c62e4'	System	10 Nov 2020 23:58:44
User entered 'No (N)'	System	10 Nov 2020 23:58:44

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-10T17:58:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7563f445-09fc-43ca-a51d-d9e7731c62e4'	System	10 Nov 2020 23:58:44
User entered '10 Nov 2020 17:58'	System	10 Nov 2020 23:58:44

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 01:13:47

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	09 Nov 2020 19:49:27
User entered 'Day 64'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b97ebaeb-db41-4b54-bc04-058c2cc27e27'	System	11 Nov 2020 21:57:39
User entered 'No (N)'	System	11 Nov 2020 21:57:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-11T15:57:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b97ebaeb-db41-4b54-bc04-058c2cc27e27'	System	11 Nov 2020 21:57:39
User entered '11 Nov 2020 15:57'	System	11 Nov 2020 21:57:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 19:49:27

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	10 Nov 2020 23:58:39
User entered 'Day 65'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:18:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9563662a-77cb-4933-bcb2-24cda6bbade6'	System	12 Nov 2020 22:18:22
User entered 'No (N)'	System	12 Nov 2020 22:18:22

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-12T16:18:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9563662a-77cb-4933-bcb2-24cda6bbade6'	System	12 Nov 2020 22:18:22
User entered '12 Nov 2020 16:18'	System	12 Nov 2020 22:18:22

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 23:58:39

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Nov 2020 21:57:33
User entered 'Day 66'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4569e413-26cf-477f-a1aa-d8a2fdc6a778'	System	14 Nov 2020 02:11:40
User entered 'No (N)'	System	14 Nov 2020 02:11:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-13T20:11:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4569e413-26cf-477f-a1aa-d8a2fdc6a778'	System	14 Nov 2020 02:11:40
User entered '13 Nov 2020 20:11'	System	14 Nov 2020 02:11:40

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 21:57:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	12 Nov 2020 22:18:12
User entered 'Day 67'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:02:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '80d397d2-74e5-4601-978f-b0dbc2665b72'	System	14 Nov 2020 20:02:09
User entered 'No (N)'	System	14 Nov 2020 20:02:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-14T14:02:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '80d397d2-74e5-4601-978f-b0dbc2665b72'	System	14 Nov 2020 20:02:09
User entered '14 Nov 2020 14:02'	System	14 Nov 2020 20:02:09

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 22:18:12

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Nov 2020 02:11:33
User entered 'Day 68'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:10:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bfc18f97-120e-4956-a268-1f65777cc8a9'	System	15 Nov 2020 18:10:17
User entered 'No (N)'	System	15 Nov 2020 18:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T12:10:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'bfc18f97-120e-4956-a268-1f65777cc8a9'	System	15 Nov 2020 18:10:17
User entered '15 Nov 2020 12:10'	System	15 Nov 2020 18:10:17

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 02:11:33

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	14 Nov 2020 20:02:06
User entered 'Day 69'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:43:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7c35e2c8-f4f9-4378-8d09-bf195cbe1623'	System	16 Nov 2020 18:43:11
User entered 'No (N)'	System	16 Nov 2020 18:43:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-16T12:43:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7c35e2c8-f4f9-4378-8d09-bf195cbe1623'	System	16 Nov 2020 18:43:11
User entered '16 Nov 2020 12:43'	System	16 Nov 2020 18:43:11

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '16 Nov 2020 12:00'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Nov 2020 11:59'	System	14 Nov 2020 20:02:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	15 Nov 2020 18:10:08
User entered 'Day 70'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '92399ea6-10a7-403a-9e12-f41cc3835ac7'	System	17 Nov 2020 19:21:48
User entered 'No (N)'	System	17 Nov 2020 19:21:48

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-17T13:21:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '92399ea6-10a7-403a-9e12-f41cc3835ac7'	System	17 Nov 2020 19:21:48
User entered '17 Nov 2020 13:21'	System	17 Nov 2020 19:21:48

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 18:10:08

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	16 Nov 2020 18:42:58
User entered 'Day 71'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:46:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7318413-15cb-4b96-b1b2-03ab3038066a'	System	18 Nov 2020 19:46:14
User entered 'No (N)'	System	18 Nov 2020 19:46:14

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-18T13:46:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'b7318413-15cb-4b96-b1b2-03ab3038066a'	System	18 Nov 2020 19:46:14
User entered '18 Nov 2020 13:46'	System	18 Nov 2020 19:46:14

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 18:42:58

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	17 Nov 2020 19:21:37
User entered 'Day 72'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '019c5eb0-2e57-4d7d-b0b5-633951519054'	System	20 Nov 2020 12:53:57
User entered 'No (N)'	System	20 Nov 2020 12:53:57

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '019c5eb0-2e57-4d7d-b0b5-633951519054' User entered '20 Nov 2020 06:53'	System	20 Nov 2020 12:53:57
	System	20 Nov 2020 12:53:57

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '19 Nov 2020 12:00'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Nov 2020 11:59'	System	17 Nov 2020 19:21:37

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	18 Nov 2020 19:46:06
User entered 'Day 73'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:16:12', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16b0df89-497c-4c2c-b812-bd3b74ae819c'	System	21 Nov 2020 04:16:13
User entered 'No (N)'	System	21 Nov 2020 04:16:13

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T22:16:14', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16b0df89-497c-4c2c-b812-bd3b74ae819c' User entered '20 Nov 2020 22:16'	System	21 Nov 2020 04:16:13
	System	21 Nov 2020 04:16:13

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 19:46:06

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	20 Nov 2020 12:53:54
User entered 'Day 74'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8249b871-f4c0-40af-8d92-26e18331bbfe'	System	22 Nov 2020 03:30:57
User entered 'No (N)'	System	22 Nov 2020 03:30:57

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-21T21:30:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8249b871-f4c0-40af-8d92-26e18331bbfe'	System	22 Nov 2020 03:30:57
User entered '21 Nov 2020 21:30'	System	22 Nov 2020 03:30:57

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 12:53:54

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	21 Nov 2020 04:16:07
User entered 'Day 75'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c3c04aeb-a5a8-4e4b-a07b-442e011fb1ed'	System	22 Nov 2020 22:51:28
User entered 'No (N)'	System	22 Nov 2020 22:51:28

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-22T16:51:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c3c04aeb-a5a8-4e4b-a07b-442e011fb1ed' User entered '22 Nov 2020 16:51'	System	22 Nov 2020 22:51:28
	System	22 Nov 2020 22:51:28

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 04:16:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Nov 2020 03:30:51
User entered 'Day 76'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:14:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '69597d33-e4d9-49c5-88ab-53ff42ee1ad6'	System	23 Nov 2020 18:14:07
User entered 'No (N)'	System	23 Nov 2020 18:14:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-23T12:14:07', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '69597d33-e4d9-49c5-88ab-53ff42ee1ad6'	System	23 Nov 2020 18:14:07
User entered '23 Nov 2020 12:14'	System	23 Nov 2020 18:14:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 03:30:51

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	22 Nov 2020 22:51:22
User entered 'Day 77'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:46:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd899056f-992b-44af-a7e7-19df4f53bfbf'	System	24 Nov 2020 22:46:07
User entered 'No (N)'	System	24 Nov 2020 22:46:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-24T16:46:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd899056f-992b-44af-a7e7-19df4f53bfbf' User entered '24 Nov 2020 16:46'	System	24 Nov 2020 22:46:07
	System	24 Nov 2020 22:46:07

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '24 Nov 2020 12:00'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Nov 2020 11:59'	System	22 Nov 2020 22:51:22

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	23 Nov 2020 18:14:02
User entered 'Day 78'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 14:50:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-25T16:44:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'eeee2b39-0fe1-402a-a882-b7290c8c51b9'	System	25 Nov 2020 22:44:35
User entered 'No (N)'	System	25 Nov 2020 22:44:35

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 14:50:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-25T16:44:35', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'eeee2b39-0fe1-402a-a882-b7290c8c51b9'	System	25 Nov 2020 22:44:35
User entered '25 Nov 2020 16:44'	System	25 Nov 2020 22:44:35

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 14:50:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:14:02

US3002149

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 14:50:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:14:02

US3002149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:22

US3002149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:22

US3002149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:22

US3002149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:22

US3002149

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:46:30

US3002149

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'I'	System	05 Oct 2020 19:46:30

US3002149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:12

US3002149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:12

US3002149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:12

US3002149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:12

US3002149

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:15

US3002149

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '1'	System	05 Oct 2020 19:47:15

US3002149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:34

US3002149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:34

US3002149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:34

US3002149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:34

US3002149

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:36

US3002149

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered '1'	System	05 Oct 2020 19:47:36

US3002149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:46

US3002149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:46

US3002149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:47:46

US3002149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'VISIT3'	System	05 Oct 2020 19:47:46

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '10:19'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered '05 Oct 2020 10:19'	System	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '96'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'bpm'	System	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '12'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'breaths/min'	System	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '135'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'mmHg'	System	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '90'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered 'mmHg'	System	05 Oct 2020 19:48:06

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30

US3002149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30

US3002149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:14

US3002149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:14

US3002149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:26

US3002149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:26

US3002149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:10:19
User entered '10:28'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:26

US3002149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered '05 Oct 2020 10:28'	System	05 Oct 2020 19:48:26

US3002149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:48:29

US3002149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
User entered '1'	System	05 Oct 2020 19:48:29

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 64'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-11T05:59:02', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c930c220-524d-4791-af3f-78052d71895f'	System	11 Oct 2020 10:59:13
User entered 'No (N)'	System	11 Oct 2020 10:59:13

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-11T05:59:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c930c220-524d-4791-af3f-78052d71895f'	System	11 Oct 2020 10:59:13
User entered 'No (N)'	System	11 Oct 2020 10:59:13

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-11T05:59:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c930c220-524d-4791-af3f-78052d71895f' User entered '11 Oct 2020 05:59:13'	System	11 Oct 2020 10:59:13
	System	11 Oct 2020 10:59:13

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 71'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T07:05:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16c8a9f7-6109-4279-83cf-235fd9ecc157'	System	18 Oct 2020 12:06:09
User entered 'No (N)'	System	18 Oct 2020 12:06:09

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T07:06:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16c8a9f7-6109-4279-83cf-235fd9ecc157'	System	18 Oct 2020 12:06:09
User entered 'No (N)'	System	18 Oct 2020 12:06:09

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-18T07:06:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16c8a9f7-6109-4279-83cf-235fd9ecc157' User entered '18 Oct 2020 07:06:04'	System	18 Oct 2020 12:06:09
	System	18 Oct 2020 12:06:09

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 78'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T07:58:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd33d9401-30f3-4322-8765-2af3076c994c'	System	25 Oct 2020 12:58:34
User entered 'No (N)'	System	25 Oct 2020 12:58:34

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T07:58:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd33d9401-30f3-4322-8765-2af3076c994c'	System	25 Oct 2020 12:58:34
User entered 'No (N)'	System	25 Oct 2020 12:58:34

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-10-25T07:58:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd33d9401-30f3-4322-8765-2af3076c994c' User entered '25 Oct 2020 07:58:36'	System	25 Oct 2020 12:58:34
	System	25 Oct 2020 12:58:34

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 92'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T05:01:09', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2f2e610a-5c93-4069-a01f-2411d5783ff5'	System	08 Nov 2020 11:01:23
User entered 'No (N)'	System	08 Nov 2020 11:01:23

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T05:01:19', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2f2e610a-5c93-4069-a01f-2411d5783ff5'	System	08 Nov 2020 11:01:23
User entered 'No (N)'	System	08 Nov 2020 11:01:23

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-08T05:01:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2f2e610a-5c93-4069-a01f-2411d5783ff5'	System	08 Nov 2020 11:01:23
User entered '08 Nov 2020 05:01:24'	System	08 Nov 2020 11:01:23

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered 'Day 99'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T08:40:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '851d415d-77a8-4af8-982c-cf7187d31a27'	System	15 Nov 2020 14:40:22
User entered 'No (N)'	System	15 Nov 2020 14:40:22

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T08:40:15', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '851d415d-77a8-4af8-982c-cf7187d31a27'	System	15 Nov 2020 14:40:22
User entered 'No (N)'	System	15 Nov 2020 14:40:22

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-15T08:40:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '851d415d-77a8-4af8-982c-cf7187d31a27'	System	15 Nov 2020 14:40:22
User entered '15 Nov 2020 08:40:20'	System	15 Nov 2020 14:40:22

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 17:48:16

US3002149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:27:12
Data entry locked.	System	11 Aug 2020 17:48:16
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 17:48:16

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:16', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c5a02172-1f16-479c-a61c-1c64c8833e29'	System	20 Nov 2020 12:53:27
User entered 'No (N)'	System	20 Nov 2020 12:53:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:23', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c5a02172-1f16-479c-a61c-1c64c8833e29'	System	20 Nov 2020 12:53:27
User entered 'No (N)'	System	20 Nov 2020 12:53:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-20T06:53:26', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c5a02172-1f16-479c-a61c-1c64c8833e29'	System	20 Nov 2020 12:53:27
User entered '20 Nov 2020 06:53:26'	System	20 Nov 2020 12:53:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-26T00:04:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7bc7c2c-90be-47b6-984b-276c0bddbe75'	System	26 Nov 2020 06:04:49
User entered 'No (N)'	System	26 Nov 2020 06:04:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-26T00:04:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7bc7c2c-90be-47b6-984b-276c0bddbe75'	System	26 Nov 2020 06:04:49
User entered 'No (N)'	System	26 Nov 2020 06:04:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-11-26T00:04:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'd7bc7c2c-90be-47b6-984b-276c0bddbe75'	System	26 Nov 2020 06:04:49
User entered '26 Nov 2020 00:04:50'	System	26 Nov 2020 06:04:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-03T01:45:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9ad83782-7479-4558-aacd-99861a382680'	System	03 Dec 2020 07:45:52
User entered 'No (N)'	System	03 Dec 2020 07:45:52

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-03T01:45:47', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9ad83782-7479-4558-aacd-99861a382680'	System	03 Dec 2020 07:45:52
User entered 'No (N)'	System	03 Dec 2020 07:45:52

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-03T01:45:52', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9ad83782-7479-4558-aacd-99861a382680'	System	03 Dec 2020 07:45:52
User entered '03 Dec 2020 01:45:52'	System	03 Dec 2020 07:45:52

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-14T18:28:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16ada0cf-540a-4769-a9bf-a211b504929a'	System	15 Dec 2020 00:28:35
User entered 'No (N)'	System	15 Dec 2020 00:28:35

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-14T18:28:25', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16ada0cf-540a-4769-a9bf-a211b504929a'	System	15 Dec 2020 00:28:35
User entered 'No (N)'	System	15 Dec 2020 00:28:35

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-14T18:28:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '16ada0cf-540a-4769-a9bf-a211b504929a'	System	15 Dec 2020 00:28:35
User entered '14 Dec 2020 18:28:28'	System	15 Dec 2020 00:28:35

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-17T00:03:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4effe27c-f5fb-4658-964b-825edf757a60'	System	17 Dec 2020 06:03:49
User entered 'No (N)'	System	17 Dec 2020 06:03:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-17T00:03:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4effe27c-f5fb-4658-964b-825edf757a60'	System	17 Dec 2020 06:03:49
User entered 'No (N)'	System	17 Dec 2020 06:03:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-17T00:03:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '4effe27c-f5fb-4658-964b-825edf757a60'	System	17 Dec 2020 06:03:49
User entered '17 Dec 2020 00:03:48'	System	17 Dec 2020 06:03:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-24T07:36:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '70292c54-9bd4-4db1-b8d3-16265ee782ce'	System	24 Dec 2020 13:36:09
User entered 'No (N)'	System	24 Dec 2020 13:36:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-24T07:36:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '70292c54-9bd4-4db1-b8d3-16265ee782ce'	System	24 Dec 2020 13:36:09
User entered 'No (N)'	System	24 Dec 2020 13:36:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-24T07:36:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '70292c54-9bd4-4db1-b8d3-16265ee782ce'	System	24 Dec 2020 13:36:09
User entered '24 Dec 2020 07:36:08'	System	24 Dec 2020 13:36:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-31T17:44:30', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7646f8a5-5c24-4e23-9ab7-8790f164f9f0'	System	31 Dec 2020 23:44:41
User entered 'No (N)'	System	31 Dec 2020 23:44:41

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-31T17:44:34', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7646f8a5-5c24-4e23-9ab7-8790f164f9f0'	System	31 Dec 2020 23:44:41
User entered 'No (N)'	System	31 Dec 2020 23:44:41

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2020-12-31T17:44:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '7646f8a5-5c24-4e23-9ab7-8790f164f9f0'	System	31 Dec 2020 23:44:41
User entered '31 Dec 2020 17:44:37'	System	31 Dec 2020 23:44:41

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-08T10:15:33', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '017ca1fe-ebfe-40ab-b3be-9600be8e5322'	System	08 Jan 2021 16:15:46
User entered 'No (N)'	System	08 Jan 2021 16:15:46

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-08T10:15:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '017ca1fe-ebfe-40ab-b3be-9600be8e5322'	System	08 Jan 2021 16:15:46
User entered 'No (N)'	System	08 Jan 2021 16:15:46

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-08T10:15:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '017ca1fe-ebfe-40ab-b3be-9600be8e5322'	System	08 Jan 2021 16:15:46
User entered '08 Jan 2021 10:15:43'	System	08 Jan 2021 16:15:46

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-14T07:47:41', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2c2d54cc-9a1a-4eea-93fd-6f97f6a62b8f'	System	14 Jan 2021 13:47:49
User entered 'No (N)'	System	14 Jan 2021 13:47:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-14T07:47:45', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2c2d54cc-9a1a-4eea-93fd-6f97f6a62b8f'	System	14 Jan 2021 13:47:49
User entered 'No (N)'	System	14 Jan 2021 13:47:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-14T07:47:48', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2c2d54cc-9a1a-4eea-93fd-6f97f6a62b8f' User entered '14 Jan 2021 07:47:48'	System	14 Jan 2021 13:47:49
	System	14 Jan 2021 13:47:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-21T07:28:56', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '14d7a09c-aea6-422c-a351-ecc5ccd768ff'	System	21 Jan 2021 13:29:09
User entered 'No (N)'	System	21 Jan 2021 13:29:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-21T07:29:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '14d7a09c-aea6-422c-a351-ecc5ccd768ff'	System	21 Jan 2021 13:29:09
User entered 'No (N)'	System	21 Jan 2021 13:29:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-21T07:29:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '14d7a09c-aea6-422c-a351-ecc5ccd768ff' User entered '21 Jan 2021 07:29:04'	System	21 Jan 2021 13:29:09
	System	21 Jan 2021 13:29:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-28T07:21:39', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9a9b355d-2c49-4708-bb9d-8d7391033cc2'	System	28 Jan 2021 13:21:48
User entered 'No (N)'	System	28 Jan 2021 13:21:48

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-28T07:21:42', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9a9b355d-2c49-4708-bb9d-8d7391033cc2'	System	28 Jan 2021 13:21:48
User entered 'No (N)'	System	28 Jan 2021 13:21:48

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-01-28T07:21:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '9a9b355d-2c49-4708-bb9d-8d7391033cc2'	System	28 Jan 2021 13:21:48
User entered '28 Jan 2021 07:21:46'	System	28 Jan 2021 13:21:48

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-04T20:48:29', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c14d3e87-53ea-4d00-9d38-559282a29de6'	System	05 Feb 2021 02:48:43
User entered 'No (N)'	System	05 Feb 2021 02:48:43

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-04T20:48:37', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c14d3e87-53ea-4d00-9d38-559282a29de6'	System	05 Feb 2021 02:48:43
User entered 'No (N)'	System	05 Feb 2021 02:48:43

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-04T20:48:40', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'c14d3e87-53ea-4d00-9d38-559282a29de6'	System	05 Feb 2021 02:48:43
User entered '04 Feb 2021 20:48:40'	System	05 Feb 2021 02:48:43

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-11T08:14:18', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '690b0a97-39fc-4e00-986d-ec5da28ce06d'	System	11 Feb 2021 14:14:21
User entered 'No (N)'	System	11 Feb 2021 14:14:21

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-11T08:14:20', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '690b0a97-39fc-4e00-986d-ec5da28ce06d'	System	11 Feb 2021 14:14:21
User entered 'No (N)'	System	11 Feb 2021 14:14:21

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-11T08:14:24', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '690b0a97-39fc-4e00-986d-ec5da28ce06d'	System	11 Feb 2021 14:14:21
User entered '11 Feb 2021 08:14:24'	System	11 Feb 2021 14:14:21

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-18T05:49:04', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2498a968-1449-4ba6-9d05-185f84bbbe43'	System	18 Feb 2021 11:49:13
User entered 'No (N)'	System	18 Feb 2021 11:49:13

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-18T05:49:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2498a968-1449-4ba6-9d05-185f84bbbe43'	System	18 Feb 2021 11:49:13
User entered 'No (N)'	System	18 Feb 2021 11:49:13

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-18T05:49:10', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2498a968-1449-4ba6-9d05-185f84bbbe43'	System	18 Feb 2021 11:49:13
User entered '18 Feb 2021 05:49:10'	System	18 Feb 2021 11:49:13

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-25T00:17:06', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ad71a319-8eb8-4bd8-a1cc-401a76b34e7a'	System	25 Feb 2021 06:17:17
User entered 'No (N)'	System	25 Feb 2021 06:17:17

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-25T00:17:08', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ad71a319-8eb8-4bd8-a1cc-401a76b34e7a'	System	25 Feb 2021 06:17:17
User entered 'No (N)'	System	25 Feb 2021 06:17:17

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-25T00:17:13', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'ad71a319-8eb8-4bd8-a1cc-401a76b34e7a' User entered '25 Feb 2021 00:17:13'	System	25 Feb 2021 06:17:17
	System	25 Feb 2021 06:17:17

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-04T09:00:27', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '19f87947-0be5-4abc-87ee-2b02f7fe1e66'	System	04 Mar 2021 15:00:39
User entered 'No (N)'	System	04 Mar 2021 15:00:39

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-04T09:00:28', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '19f87947-0be5-4abc-87ee-2b02f7fe1e66'	System	04 Mar 2021 15:00:39
User entered 'No (N)'	System	04 Mar 2021 15:00:39

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-04T09:00:32', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '19f87947-0be5-4abc-87ee-2b02f7fe1e66'	System	04 Mar 2021 15:00:39
User entered '04 Mar 2021 09:00:32'	System	04 Mar 2021 15:00:39

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-11T07:29:50', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a94754cc-77d5-4382-bfb0-a3fae24a1bb4'	System	11 Mar 2021 13:29:59
User entered 'No (N)'	System	11 Mar 2021 13:29:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-11T07:29:54', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a94754cc-77d5-4382-bfb0-a3fae24a1bb4'	System	11 Mar 2021 13:29:59
User entered 'No (N)'	System	11 Mar 2021 13:29:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-11T07:29:57', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a94754cc-77d5-4382-bfb0-a3fae24a1bb4'	System	11 Mar 2021 13:29:59
User entered '11 Mar 2021 07:29:57'	System	11 Mar 2021 13:29:59

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-18T12:18:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8c4b36c7-3c25-4add-ba9d-72129aae2423'	System	18 Mar 2021 17:18:13
User entered 'No (N)'	System	18 Mar 2021 17:18:13

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-18T12:18:03', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8c4b36c7-3c25-4add-ba9d-72129aae2423'	System	18 Mar 2021 17:18:13
User entered 'No (N)'	System	18 Mar 2021 17:18:13

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-18T12:18:05', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '8c4b36c7-3c25-4add-ba9d-72129aae2423'	System	18 Mar 2021 17:18:13
User entered '18 Mar 2021 12:18:05'	System	18 Mar 2021 17:18:13

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-25T13:27:36', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2421a75b-4a73-4358-b856-79adb998d888'	System	25 Mar 2021 18:27:51
User entered 'No (N)'	System	25 Mar 2021 18:27:51

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-25T13:27:43', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2421a75b-4a73-4358-b856-79adb998d888'	System	25 Mar 2021 18:27:51
User entered 'No (N)'	System	25 Mar 2021 18:27:51

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-03-25T13:27:46', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2421a75b-4a73-4358-b856-79adb998d888'	System	25 Mar 2021 18:27:51
User entered '25 Mar 2021 13:27:46'	System	25 Mar 2021 18:27:51

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-01T09:02:02-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe40ebfa-33b5-440a-bdfb-8ec5cc56ccfe'	System	01 Apr 2021 14:02:10
User entered 'No (N)'	System	01 Apr 2021 14:02:10

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-01T09:02:07-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe40ebfa-33b5-440a-bdfb-8ec5cc56ccfe'	System	01 Apr 2021 14:02:10
User entered 'No (N)'	System	01 Apr 2021 14:02:10

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-01T09:02:10-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'fe40ebfa-33b5-440a-bdfb-8ec5cc56ccfe' User entered '01 Apr 2021 09:02:10'	System	01 Apr 2021 14:02:10
	System	01 Apr 2021 14:02:10

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-08T00:17:54-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '49a5ebd7-2341-4c48-ab6a-fb853e392750'	System	08 Apr 2021 05:18:02
User entered 'No (N)'	System	08 Apr 2021 05:18:02

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-08T00:17:57-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '49a5ebd7-2341-4c48-ab6a-fb853e392750'	System	08 Apr 2021 05:18:02
User entered 'No (N)'	System	08 Apr 2021 05:18:02

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-08T00:18:00-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '49a5ebd7-2341-4c48-ab6a-fb853e392750'	System	08 Apr 2021 05:18:02
User entered '08 Apr 2021 00:18:00'	System	08 Apr 2021 05:18:02

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-15T04:30:33-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb85e3f4-44c6-4472-afc4-99e16021190b'	System	15 Apr 2021 09:31:27
User entered 'Yes (Y)'	System	15 Apr 2021 09:31:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-15T04:30:45-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb85e3f4-44c6-4472-afc4-99e16021190b'	System	15 Apr 2021 09:31:27
User entered 'No (N)'	System	15 Apr 2021 09:31:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-15T04:30:51-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb85e3f4-44c6-4472-afc4-99e16021190b'	System	15 Apr 2021 09:31:27
User entered 'No (N)'	System	15 Apr 2021 09:31:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-15T04:31:06-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb85e3f4-44c6-4472-afc4-99e16021190b'	System	15 Apr 2021 09:31:27
User entered 'Yes (Y)'	System	15 Apr 2021 09:31:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-15T04:31:13-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb85e3f4-44c6-4472-afc4-99e16021190b'	System	15 Apr 2021 09:31:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Apr 2021 09:31:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-15T04:31:17-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'cb85e3f4-44c6-4472-afc4-99e16021190b'	System	15 Apr 2021 09:31:27
User entered '15 Apr 2021 04:31:17'	System	15 Apr 2021 09:31:27

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-22T06:56:31-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a7040b59-a1d2-4e55-9b1b-f5fbf6de75e0'	System	22 Apr 2021 11:56:46
User entered 'No (N)'	System	22 Apr 2021 11:56:46

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-22T06:56:34-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a7040b59-a1d2-4e55-9b1b-f5fbf6de75e0'	System	22 Apr 2021 11:56:46
User entered 'No (N)'	System	22 Apr 2021 11:56:46

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-22T06:56:38-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: 'a7040b59-a1d2-4e55-9b1b-f5fbf6de75e0'	System	22 Apr 2021 11:56:46
User entered '22 Apr 2021 06:56:38'	System	22 Apr 2021 11:56:46

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-29T06:33:02-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2da2009c-2401-4265-9542-7a4afd634ae8'	System	29 Apr 2021 11:33:09
User entered 'No (N)'	System	29 Apr 2021 11:33:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-29T06:33:06-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2da2009c-2401-4265-9542-7a4afd634ae8'	System	29 Apr 2021 11:33:09
User entered 'No (N)'	System	29 Apr 2021 11:33:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-04-29T06:33:09-05:00', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '2da2009c-2401-4265-9542-7a4afd634ae8'	System	29 Apr 2021 11:33:09
User entered '29 Apr 2021 06:33:09'	System	29 Apr 2021 11:33:09

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:53:49

US3002149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:49
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:53:49

US3002149

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:50:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:58:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-27T15:21:53', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '99130290-a8c9-476d-813f-f88e39be7c7b'	System	27 Feb 2021 21:22:05
User entered 'No (N)'	System	27 Feb 2021 21:22:05

US3002149

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:50:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:58:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a819bd0e264d58)', Time: '2021-02-27T15:22:01', User OID: 'PatientReportedOutcome (US3002149)', ODM File OID: '99130290-a8c9-476d-813f-f88e39be7c7b'	System	27 Feb 2021 21:22:05
User entered '27 Feb 2021 15:22:01'	System	27 Feb 2021 21:22:05

US3002149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:11:33

US3002149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:11:33

US3002149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:11:33

US3002149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:11:33

US3002149

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:11:37

US3002149

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 01:58:19
User entered 'I'	System	09 Dec 2020 14:11:37

US3002149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered 'Yes (Y)'	(b) (4) Jessica Satorie (b) (4)	28 Mar 2021 21:17:56

US3002149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered '07 Dec 2020'	Jessica Satorie (b) (4)	28 Mar 2021 21:17:56

US3002149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	28 Mar 2021 21:17:56

US3002149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered empty.	(b) (4) Jessica Satorie (b) (4)	28 Mar 2021 21:17:56

US3002149

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:28:51

US3002149

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered '1'	System	07 Jan 2021 19:28:51

US3002149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:29:03

US3002149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '06 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:29:03

US3002149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:29:03

US3002149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:29:03

US3002149

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:29:06

US3002149

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered '1'	System	07 Jan 2021 19:29:06

US3002149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	28 Mar 2021 21:18:17

US3002149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered '08 Feb 2021'	Jessica Satorie (b) (4)	28 Mar 2021 21:18:17

US3002149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	28 Mar 2021 21:18:17

US3002149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered empty.	(b) (4) Jessica Satorie (b) (4)	28 Mar 2021 21:18:17

US3002149

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	28 Mar 2021 21:18:23

US3002149

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered 'I'	System	28 Mar 2021 21:18:23

US3002149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	28 Mar 2021 23:26:52

US3002149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered '23 Feb 2021'	(b) (4) Tiffany Nemecek (b) (4)	28 Mar 2021 23:26:52

US3002149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[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 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
Signature has been broken.	(b) (4) Jessica Satorie (b) (4)	02 Apr 2021 23:46:46
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4) Jessica Satorie (b) (4)	02 Apr 2021 23:46:46
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:56
User entered 'Home (Home)'	(b) (4) Tiffany Nemecek (b) (4)	28 Mar 2021 23:26:52

US3002149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered 'VISIT4'	System	28 Mar 2021 23:26:52

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered 'No (N)'	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered empty.	System	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered empty.	System	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	(b) (4) Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered empty.	System	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered empty.	System	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered empty.	System	02 Apr 2021 23:46:38

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59

US3002149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59

US3002149

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered 'No (N)'	(b) (4) Jessica Satorie (b) (4)	02 Apr 2021 23:47:16

US3002149

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered empty.	Jessica Satorie (b) (4)	02 Apr 2021 23:47:16

US3002149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	02 Apr 2021 23:47:31

US3002149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered '23 Feb 2021'	Jessica Satorie (b) (4)	02 Apr 2021 23:47:31

US3002149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered '16:27'	Jessica Satorie (b) (4)	02 Apr 2021 23:47:31

US3002149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered '23 Feb 2021 16:27'	System	02 Apr 2021 23:47:31

US3002149

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User signature succeeded.	Brandon Essink (b) (4)	05 Apr 2021 04:08:05
User entered 'Yes (Y)'	(b) (4) Jessica Satorie (b) (4)	02 Apr 2021 23:47:40

US3002149

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:51:59
User entered '1'	System	02 Apr 2021 23:47:40

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:12:46

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:12:46

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:12:46

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User entered 'UNBLND_DECIDE'	System	24 Feb 2021 18:12:46

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:44:50
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:13:56

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:44:50
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:13:56

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Date of unblinding \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User entered empty.	System	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User entered empty.	System	24 Feb 2021 18:13:07

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:16

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:16

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered '16:27'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:16

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User entered '23 Feb 2021 16:27'	System	24 Feb 2021 18:13:16

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:25

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:25

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:16:28
User entered '16:28'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:25

US3002149

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:12

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:16
User entered '23 Feb 2021 16:28'	System	24 Feb 2021 18:13:25

US3002149

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:50:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:19:11
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:23:50
Signature has been broken.	Jessica Satorie (b) (4)	20 Apr 2021 20:31:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jessica Satorie (b) (4)	20 Apr 2021 20:31:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:26:24

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Haematochezia, LLT: Hematochezia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:35:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:35:31
Data point term sent to Coder	System	20 Apr 2021 20:34:24
User entered 'hematochezia'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '09 Apr 2021'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Not Related (NOT RELATED)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Not Related (NOT RELATED)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '1'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 20:33:33

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:39:13
User entered 'USA-US005-2021-mRNA-1273-P301000011'	System	21 Apr 2021 15:38:22
User entered 'New'	(b) (4), (b) (6)	21 Apr 2021 15:38:22

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLT: Gastrointestinal neoplasms malignant and unspecified, HLT: Oesophageal neoplasms malignant, PT: Oesophageal carcinoma, LLT: Esophageal cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:39:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:39:32
Data point term sent to Coder	System	20 Apr 2021 20:38:44
User entered 'esophageal cancer'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	01 May 2021 11:48:55
User closed query 'PV Query: As the treatment of the event (15 Apr 2021) was started before the onset date of the event (19 Apr 2021), therefore please consider updating the event onset date to the date when first signs and symptoms appeared. ' (Site from Safety). Query 'PV Query: As the treatment of the event (15 Apr 2021) was started before the onset date of the event (19 Apr 2021), therefore please consider updating the event onset date to the date when first signs and symptoms appeared. ' answered with 'updated' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:14:22
DataPoint Un-verified.	Jessica Satorie (b) (4)	29 Apr 2021 16:55:01
Signature has been broken.	Jessica Satorie (b) (4)	29 Apr 2021 16:54:44
User entered '09 Apr 2021' reason for change: Data Entry Error	Jessica Satorie (b) (4)	29 Apr 2021 16:54:44
User opened query 'PV Query: As the treatment of the event (15 Apr 2021) was started before the onset date of the event (19 Apr 2021), therefore please consider updating the event onset date to the date when first signs and symptoms appeared. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 01:08:28
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '19 Apr 2021'	Jessica Satorie (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
DataPoint Un-verified.	(b) (4)	
	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
	(b) (4)	
Signature has been broken.	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
	(b) (4)	
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Grade 4 (Grade 4)'	Jessica Satorie (b) (4)	20 Apr 2021 20:37:51
	(b) (4)	

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
DataPoint Un-verified.	(b) (4)	
	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
	(b) (4)	
Signature has been broken.	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
	(b) (4)	
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '1'	Jessica Satorie (b) (4)	20 Apr 2021 20:37:51
	(b) (4)	

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
DataPoint Un-verified.	(b) (4)	
	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
Signature has been broken.	(b) (4)	
	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Jessica Satorie (b) (4)	22 Apr 2021 15:41:17
User signature succeeded.	(b) (4)	
	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'		
	Jessica Satorie (b) (4)	20 Apr 2021 20:37:51
	(b) (4)	

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Not Related (NOT RELATED)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Not Related (NOT RELATED)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '1'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:14:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:14:54
User closed query 'PV Query: Did the subject have any family history of the cancers? ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:14:51
Query 'PV Query: Did the subject have any family history of the cancers? ' answered with 'awaiting medical records' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	29 Apr 2021 16:54:15
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'awaiting medical records' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	29 Apr 2021 16:53:56
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'awaiting medical records' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	29 Apr 2021 16:53:33
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 01:08:52
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 01:08:44
User opened query 'PV Query: Did the subject have any family history of the cancers? ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 01:08:37
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:19:23
User entered 'Patient got confirmed diagnosis of esophageal cancer on 4/19/2021. He reported that it is not operable and was given 2-5 months to live. Med record release form mailed to patient for records.'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 20:37:51

US3002149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 20:37:51

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:50:12

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User closed query 'Per CDM: Per the participant response for diary dose 2 (09Sep2020) medication was taken to treat pain (or) fever for Day 1 to Day 43 is reported on diary dose, however there is no corresponding Medication reported within this Start and stop dates. Please review and update accordingly. Else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 10:24:07
User closed query 'Per CDM: Per the participant response for diary dose 1(11Aug2020) medication was taken to treat pain (or) fever for Day 1 and Day3 to Day30 is reported on diary dose, however there is no corresponding Medication reported within this Start and stop dates. Please review and update accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:24:04
Query 'Per CDM: Per the participant response for diary dose 2 (09Sep2020) medication was taken to treat pain (or) fever for Day 1 to Day 43 is reported on diary dose, however there is no corresponding Medication reported within this Start and stop dates. Please review and update accordingly. Else clarify' answered with 'Pt. is a double amputee and takes medicine everyday ' (Site from DM).	Tiffany Nemecek (b) (4) (b) (4)	22 Oct 2020 13:56:55
Query 'Per CDM: Per the participant response for diary dose 1(11Aug2020) medication was taken to treat pain (or) fever for Day 1 and Day3 to Day30 is reported on diary dose, however there is no corresponding Medication reported within this Start and stop dates. Please review and update accordingly. Else clarify' answered with 'Pt. is a double amputee and takes medicine everyday ' (Site from DM).	Tiffany Nemecek (b) (4) (b) (4)	22 Oct 2020 13:56:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:50:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per the participant response for diary dose 2 (09Sep2020) medication was taken to treat pain (or) fever for Day 1 to Day 43 is reported on diary dose, however there is no corresponding Medication reported within this Start and stop dates. Please review and update accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:55:52
User opened query 'Per CDM: Per the participant response for diary dose 1(11Aug2020) medication was taken to treat pain (or) fever for Day 1 and Day3 to Day30 is reported on diary dose, however there is no corresponding Medication reported within this Start and stop dates. Please review and update accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:50:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 13:10:21

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Oct 2020 19:50:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Oct 2020 19:50:22
Data point term sent to Coder Coding entries removed.	System	05 Oct 2020 19:49:15
	(b) (4), (b) (6)	05 Oct 2020 19:49:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Aug 2020 16:32:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Aug 2020 16:32:21
Data point term sent to Coder	System	12 Aug 2020 13:11:31
User entered 'Pantoprazole'	(b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'PEPTIC ULCER DISEASE' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:49:00
User entered 'Peptic ulcer'	(b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '40'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User closed 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).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 08:47:40
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.' answered with 'Data correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:11:22
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	12 Aug 2020 13:11:16
User entered '10 Jul 2020'	(b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 13:11:16

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 22:51:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 22:51:37
Data point term sent to Coder	System	21 Oct 2020 20:36:49
User entered 'ibuprofen'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49
	(b) (4)	

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Bilateral leg amputation'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '800'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'mg (mg)'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49
	(b) (4)	

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'as needed (PRN)'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49
	(b) (4)	

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Oral (ORAL)'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'un UNK 2016'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered '0'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered empty.	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:24
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	Tiffany Nemecek (b) (4)	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:35:49

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:57:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:57:03
Data point term sent to Coder	System	20 Apr 2021 20:45:04
User entered 'sucralfate'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'esophageal cancer'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered '10000000'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'mg (mg)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'four times daily (QID)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'Oral (ORAL)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered '15 Apr 2021'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 20:44:30

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:58:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:58:07
Data point term sent to Coder	System	20 Apr 2021 20:46:06
User entered 'tramadol'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'esophageal cancer'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered '50'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'mg (mg)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'as needed (PRN)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'Oral (ORAL)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered '15 Apr 2021'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered '0'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:24:24
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 20:45:26

US3002149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:50:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:24:39
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:08:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 16:26:18

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'USA-US005-2021-MRNA-1273-P301000011'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'No (N)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'Yes (Y)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Brandon'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Essink'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '3319 N 107th'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Omaha'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '68134'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:59:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
User entered 'US'	(b) (4) System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 15:16:26
User entered '2'	System	22 Apr 2021 18:02:32
User entered '1'	System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'USA-US005-2021-MRNA-1273-P301000011'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'No (N)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'Yes (Y)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Brandon'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Essink'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '3319 N 107th'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Omaha'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '68134'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:59:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
User entered 'US'	(b) (4) System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 15:16:26
User entered '2'	System	22 Apr 2021 18:02:32
User entered '1'	System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:50:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
User entered '21/Apr/2021 11:43'	(b) (4) System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:50:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:59:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'USA-US005-2021-MRNA-1273-P301000011'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'No (N)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'Yes (Y)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Brandon'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Essink'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '3319 N 107th'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Omaha'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '68134'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:59:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
User entered 'US'	(b) (4) System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 15:16:26
User entered '2'	System	22 Apr 2021 18:02:32
User entered '1'	System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:50:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
User entered '22/Apr/2021 14:02'	(b) (4) System	22 Apr 2021 18:02:32

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:50:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 15:16:00
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
User entered '1'	(b) (4), (b) (6)	22 Apr 2021 18:02:32

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'USA-US005-2021-MRNA-1273-P301000011'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'No (N)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Yes (Y)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:00:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:17
Un-reviewed for Safety.	System	22 Apr 2021 15:41:17
Signature has been broken.	System	22 Apr 2021 15:41:17
User entered 'Yes (Y)'	System	22 Apr 2021 15:41:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'No (N)'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Brandon'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Essink'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '3319 N 107th'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered 'Omaha'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:43:01
User entered '68134'	System	21 Apr 2021 15:38:22

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:59:17
User signature succeeded.	Brandon Essink (b) (4)	22 Apr 2021 15:24:28
User entered 'US'	(b) (4) System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 15:16:26
User entered '2'	System	22 Apr 2021 18:02:32
User entered '1'	System	21 Apr 2021 15:43:07

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:50:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	01 May 2021 11:48:55
User entered '30/Apr/2021 11:16'	(b) (4) System	30 Apr 2021 15:16:26

US3002149

Folder: SAE USA-US005-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:50:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	01 May 2021 11:48:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:16:26